EXHIBIT E

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	) Master File No. 2:12-MD-02327) MDL No. 2327)
THIS DOCUMENT RELATES TO ALL WAVE 4 PLAINTIFFS	) JOSEPH R. GOODWIN) U.S. DISTRICT JUDGE)

DEPOSITION OF TED M. ROTH, M.D.

(TVT and TVT-O General)

Deposition of TED M. ROTH, M.D., taken before Beth Gaige, RPR, Notary Public in and for the State of Maine, pursuant to notice dated March 13, 2017, at the Embassy Suites Hotel by Hilton, 1050 Westbrook Street, Portland, Maine, on March 16, 2017, commencing at 9:59 a.m.

APPEARANCES

For the Plaintiff:

Andrew N. Faes, Esq.
WAGSTAFF & CARTMELL, LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
816.701.1100
afaes@wcllp.com

For the Defendant:

Diana Katz Gerstel, Esq.
Riker Danzig
Headquarters Plaza
One Speedwell Avenue
Morristown, NJ 07962-1981
973.451.8468
dgerstel@riker.com

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TRANSCRIPT OF PROCEEDINGS

TED M. ROTH, M.D., having been duly sworn by the Notary Public, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. FAES:

Q. Good morning, Dr. Roth.
A. Morning.
Q. My name is Andy Faes, and I represent various plaintiffs in this litigation, and I'm here today to take your deposition regarding your opinions on the TVT and TVT-O.
Do you understand that?
A. Yes.
Q. And you understand that you're under oath and must tell the truth, right?
A. Yes.
Q. If I ask you a question any time today that you don't understand, please feel free to let me know, and I'll try to rephrase the question. Otherwise, if you answer the question, I'll assume that you understood the question as asked.

Fair enough?
A. Yeah.
Q. You've been deposed before, right?
A. I have.
Q. How many times?
A. Twice.
Q. And one of those cases was a case involving an Ethicon pelvic mesh product, right?
A. As a -- yes. I was an implanter.
Q. And what was the other case?
A. The other case was a med mal case.
Q. And what was your role in that case?
A. The defendant.
Q. And what was -- what did that case involve?
A. The nature of the case was a claim of delayed diagnosis.
Do you need details of the facts?
Q. What -- well, first of all, when approximately did this occur?
A. 2007. And it involved an elderly woman with hematuria, and they claimed delayed diagnosis in advanced bladder cancer.
Q. And what was the resolution of that case?

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A. It was settled.
Q. Did that case involve a pelvic mesh at all?
A. No.
Q. Do you recall who the -- who any of the lawyers were who were involved in that case?
A. It was a local law firm from Maine.
Q. And that kind of leads into my next question.
Have you ever been a party to a lawsuit before, other than that case?
A. I was named in one, two -- two suits from my time during residency at Duke, and I was dropped from both of those without any sort of, you know, payment or settlement.
And then I was a defendant in another case in Mississippi, and that is kind of ongoing, unfortunately.
Q. Okay. What is the -- what's the case in Mississippi involve?
A. The case in Mississippi was I was working at a planned parenthood-like clinic, and the patient claims that I improperly performed termination of pregnancy.

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And that case is sort of ongoing, or there's issues with the case that I -- I can't discuss; let's just say that.
Q. Okay. When did the procedure that's the subject of the lawsuit take place?
A. March of 2004 or -- I think it was March of 2004.
Q. Okay. I'm going to hand you what's been marked as Exhibit No. 1 to your deposition.
(Deposition Exhibit No. 1 was marked for identification.)
BY MR. FAES:
Q. And that's the notice of your deposition here today.
Have you ever seen that document before?
A. (Examining document) I have not.
Q. So you haven't had an opportunity to review any of the various document requests or -- and requests for production of documents that are attached to this notice?
A. I -- I don't think I've seen a formal notice of my deposition today, no.
Q. Have you brought any materials or items with you here today for this deposition?

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A. I have my report, and I have selected medical literature, and I think that Diana has my CV.
MS. KATZ GERSTEL: And I'll just say for the record that we filed a response to this notice yesterday.
MR. FAES: I know you did.
BY MR. FAES:
Q. Have you brought any bills or invoices for your work in this case?
A. I have not, no.
Q. Have you billed or invoiced any of your work in this case yet?
A. When you say in this case, you mean for the production of the report or for various cases that I have reviewed?
Q. I'm specifically talking about your invoices for the TVT and TVT-O general report that we're here today to discuss.
A. I have, yes.
Q. And approximately how many hours have you billed so far today?
A. Geez --
MS. KATZ GERSTEL: You know, can I just say that I actually brought invoices.

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MR. FAES: Okay.
MS. KATZ GERSTEL: They're not broken down by TVT, TVT-O, but I have invoices.
MR. FAES: Okay. I'm going to mark Exhibit 1-A to your deposition, and I am -- for the record this is the invoices that counsel has brought with her to the deposition today.
(Deposition Exhibit No. 1-A was marked for identification.)
BY MR. FAES:
Q. Doctor, do these represent the various invoices that you've submitted for your work as a litigation consultant with Ethicon and Johnson & Johnson regarding the pelvic mesh?
A. (Examining document) I mean, they're not the exact bills I submitted, but I guess it's -- it's a distillation of those bills. The numbers look right.
Q. So, for example, the very first page of Exhibit No. 1-A, is that an invoice actually prepared by you, or is that not an invoice prepared by you?

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A. (Examining document) Well, it's -- it's not the actual -- I didn't actually type this, so it wasn't prepared by me. But I have prepared a bill that was e-mailed to Diana, and this appears to be a distillation of that.
Q. So do you know who prepared the invoice or the page 1 of Exhibit 1-A?
A. I -- I don't.
Q. It's not something that was prepared by you though, right?
A. Not by me, but it's an accurate representation of one of the bills that I submitted to Diana.
MR. FAES: Okay. Just for the record, we requested that we be provided with all of the actual bills he has submitted in this case.
BY MR. FAES:
Q. Doctor, I've only had a brief second to go through the invoices and payments marked as Exhibit 1-A.
But does it appear accurate that so far you've been paid -- or at least you billed over $125,000 for your work as a litigation consultant with Ethicon and Johnson & Johnson?

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A. That's -- I think that's fair.
Q. When were you first approached to be a litigation consultant regarding the TVT and the TVT-O products?
A. It was with -- had to be late 2014 or 2015. It was a different attorney who worked for a different firm who is no longer with, I guess, Butler Snow.
MS. KATZ GERSTEL: Doug DiPaola.
THE WITNESS: Yeah.
A. I think I was contacted by him in late 2014 or 2015 and signed an agreement at that point. I had maybe one phone conversation with him and one meeting with him, and then there was a time that went by and nothing was happening. And then I was recontacted by Diana.
BY MR. FAES:
Q. So you were first approached about potentially being a witness in late 2014 and 2015, and signed an agreement at that time, correct?
A. Yes.
Q. When did you actually start work on the TVT and TVT-O General Expert Report?
A. Let's see, I met with -- I had a phone

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conversation with Diana, met with her in Boston in May of 2016. I think that's about right. And then we had a three-hour conversation, meeting in Boston; then she told me what my deadlines were, which were pretty quick.
Q. Prior to becoming involved in this litigation as an expert witness for Ethicon and Johnson & Johnson, have you ever been an expert witness in any kind of case before?
A. Not for mesh cases, no. I've done a little bit of case reviews for one of the local law firms here in Portland, but they weren't -- they weren't mesh litigation cases. And the cases didn't proceed to the point where I was deposed. I reviewed the cases, wrote a report.
Q. And what kind of case reviews did you do for the local firm in Portland?
A. They're both -- one was a med mal case. The other was a patient complaint to the medical board about this particular surgeon, and the attorney wanted me to review the case, look at the merits of the case.

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Q. So essentially your job in those cases was to review medical records and write a report?
A. Yes.
Q. And what time frame did your -- did this case review for the local law firms in Portland take place?
A. I think one was probably in 2008. One was in 2009.
I'm actually in the middle of one, a third, currently, that I will probably be deposed on at some point, and that is -- it's sort of a quasi-mesh case. It's more of -- the accusation against the implanter was inadequate informed consent for the mesh.
Q. And what kind of a mesh was involved in that case?
A. It was an AMS product.
Q. What kind of AMS product?
A. It was the Apogee.
Q. And when was that implant -- when was the Apogee implanted in that case?
A. I think it might have been 2009, 2010.
Q. And that's ongoing, and you haven't

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issued a report in that case yet, right?
A. What's interesting for that, I met with the attorney a couple of times. We -- I read through all the records. We had a conversation. He actually generated the report. I think in Maine they don't require experts to necessarily generate a report, and so that's -- that's ongoing, so I've yet to be deposed in that matter.
Q. So am I correct that you've done approximately three case reviews for the same --
A. For the same firm.
Q. -- the same Portland firm?
What firm is that?
A. Oh, it's -- you guys always have so many names in your firms. I -- I'm blanking out on the name of the firm. It's, you know, a gazillion different last names of the firm.
Q. And of those -- and those three case reviews, was your role to write a report for the plaintiff or the defendant in those cases?
A. The attorneys were all representing the defendant. I mean, again, one of the cases

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was not -- she wasn't being sued. It was just that that law firm handles complaints to the medical board. So she wasn't -- it wasn't a suit. But the other two -- actually, the other two cases involved the same physician, and I was working on -- on his defense.
Q. So of all the cases where you've been an expert witness in litigation, it's always been for the defendant; is that accurate?
A. Correct.
Q. I'm going to hand you what's been marked as Exhibit No. 2 to your deposition, if you need it. I understand you already have a copy of it.
(Deposition Exhibit No. 2 was marked for identification.)
BY MR. FAES:
Q. Is this the TVT and TVT-O expert report that you issued in this case?
A. (Examining document) Yes.
Q. And this report covers both the TVT and the TVT-O, correct?
A. Correct.
Q. Is there any particular reason why you chose

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to issue one expert report for both the TVT and TVT-O, as opposed to doing a separate report for the TVT and a separate report for the TVT-O?
A. No particular reason.
Q. Do you feel that the TVT and the TVT-O have identical safety profiles?
A. I think that they do have identical safety profiles, but I think that some of the complications from the TVT and TVT-O are a little different based on the nature of the passage of the -- the mesh material, but I think that they're both very safe.
Q. So you'd agree then that the TVT and TVT-O have different complication rates with regard to certain complications, right?
A. They have -- yes, I would agree that they have different complication rates in regards to certain complications, yes.
Q. And despite knowing that they had these different complication rates with regard to certain complications, you still felt it was appropriate to combine all of your opinions regarding both those products in a single

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report?
MS. KATZ GERSTEL: Object to form.
A. You know, again, I think they're sort of variations of a sling technique. I think it was pretty reasonable to combine them into one report. A lot of the data, you know, compares both the retropubic and the transobturator techniques. The mesh is essentially the same. I didn't see a need to have separate reports.
BY MR. FAES:
Q. Do you believe that the TVT and TVT-O have identical efficacy profiles?
MS. KATZ GERSTEL: Object to form.
A. We have slightly longer term data for the retropubic TVT than for the TVT-O. Again, depending upon what study you read, what meta-analysis you read, I think that most of us would say that the efficacy is relatively equivalent.
BY MR. FAES:
Q. So you believe that the efficacy profile of the TVT versus the TVT-O is relatively equivalent but not equivalent?
MS. KATZ GERSTEL: Object to form.

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A. They're not exactly the same.
BY MR. FAES:
Q. Okay. And despite having the opinion that the efficacy profile between the TVT and the TVT-O is not exactly the same, you still felt it was appropriate to combine your opinions for both those products in a single report; is that accurate?
MS. KATZ GERSTEL: Object to form.
A. I -- I really didn't feel the need to write separate reports on the TVT and the TVT-O.
BY MR. FAES:
Q. Now, are you -- with regard to the TVT, are you offering opinions as to the safety and efficacy of both the mechanically-cut TVT and the laser-cut TVT?
A. I can offer opinions on both. I can tell you that in my practice, I use the mechanically-cut TVT.
Q. And you understand that the mechanically-cut and the laser-cut TVT are two distinct different products, correct?
MS. KATZ GERSTEL: Object.
A. I know that the manufacturing basis for those

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products is -- is obviously different, and I know that the -- there's labeling on the box that is different that distinguishes laser-cut from mechanically-cut. I think there's an L on the laser-cut box.
The -- the handling characteristics in my hands are very similar between the two products, but I -- I would agree with you that they're two slightly different products.
BY MR. FAES:
Q. So knowing that the TVT and the -- strike that.
Knowing that the mechanically-cut TVT and the laser-cut TVT are two distinctly different products with two distinct different order codes and identifiers, do you feel that the safety profile for the mechanically-cut TVT is identical to the safety profile for the laser-cut TVT?
MS. KATZ GERSTEL: Object to form.
A. I'm not aware of any difference in efficacy or any difference in the safety profile between the laser-cut and the mechanically-cut TVT products. I can't recall a single -- I can't

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recall a single article comparing the two in terms of efficacy or safety profile.
BY MR. FAES:
Q. So is it going to be in your opinion -- strike that.
Do you intend to offer an opinion in this case to a reasonable degree of medical certainty that the safety profile between the mechanically-cut TVT retropubic and the laser-cut TVT retropubic are identical?
A. Yes.
Q. And what is the -- what is the basis for that opinion?
A. Well, it's -- it's not based on the medical literature, because I -- again, I can't find -- I don't recall seeing a randomized controlled trial looking at laser-cut versus mechanically-cut mesh. However, I've used both products and followed patients, you know, out, and I've seen no difference in efficacy or adverse events with either product.
Q. So you'd agree that your opinion that the efficacy rate for the TVT mechanically-cut -- strike that.

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You'd agree that your opinion that the safety profile for the TVT mechanically-cut and the laser -- TVT laser-cut is identical can't be based on the medical literature because there's been no randomized controlled trial specifically comparing the safety profile of the TVT retropubic mechanically-cut versus the TVT retropubic laser-cut, correct?
MS. KATZ GERSTEL: Object to form.
A. That's a very long question.
BY MR. FAES:
Q. It is.
A. I -- I can tell you that in my experience, I've seen really no difference in the handling characteristics or in efficacy or in adverse events with the two different products.
Can I say that the efficacy is the same in my hands? Yes.
Globally, I can't make a comment on that.
Q. So your opinion that the safety profile of the TVT retropubic laser-cut and the TVT retropubic mechanically-cut are identical is based on your personal experience, not your review of the medical literature; is that

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accurate?
MS. KATZ GERSTEL: Object to form.
A. Well, my review of the medical literature -- in my review of the medical literature, I don't see -- I haven't seen a comparison trial between the two products. So my opinion is based on my personal experience.
BY MR. FAES:
Q. So since your opinion in that regard is based on your personal experience, you'd agree that it's not based on any formal analysis that you've done, correct?
MS. KATZ GERSTEL: Object to form.
A. How do you define formal analysis?
BY MR. FAES:
Q. Well, I would define formal analysis as have you specifically analyzed a number of patients -- well, strike that.
What would you define as a formal analysis?
A. I guess I'm the one who is supposed to answer the questions today.
I've -- I've gone back and done a retrospective review of my patients who have

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had laser-cut versus mechanically-cut TVTs, and I guess I'm sort of privileged in that I live in Maine and it's a small state and people tend not to, you know, leave the state or -- and they tend to come back to doctors who've implanted them. So I've had an opportunity to follow these patients out for several years, and I've not seen any difference in efficacy or any adverse events with the two different products.
Q. So your opinion that the safety profile between the mechanically-cut and the laser-cut TVT retropubic is based on your retrospective review of your own patients?
A. Of my own patients, yes.
Q. And is any of your analysis regarding your retrospective review of your patients disclosed anywhere in your expert report?
A. I don't think that I made a specific comment about my own experience with laser-cut versus mechanically-cut.
Again, I'm using mechanically-cut mesh at this point mostly because I think of a cost issue of my facility.

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But, no, I don't think that we made a specific comment as to my personal experience with laser-cut versus mechanically-cut, mostly because I don't really distinguish between the two in terms of handling characteristics, efficacy or safety.
Q. So this retrospective review that you did of mechanically-cut TVT versus laser-cut TVT, how many patients were involved?
A. It was probably at least a hundred.
Q. How many of those patients were -- well, let me follow up on that, so strike that.
Is it almost -- I mean, what -- do you know the exact number as you sit here today?
A. I mean, I could -- I could certainly get back to you on that, but I think it's a hundred patients. I probably looked at 50 and 50, just pulled them, you know, from the medical record and then referenced the implant log at the hospital.
Q. And so you've kind of anticipated my next question.
How many of these patients were laser-cut, and how many of them were

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mechanically-cut?
A. I mean, it's just a personal retrospective review. It's not published. But, you know, I was curious as to know whether there was any sort of differences between the two products. So I just, you know, looked at my experience with them and pulled 50 charts, you know, randomly from each, the laser-cut and mechanically-cut groups, and sort of looked through their records, the electronic medical record. Really no differences between -- between the two groups.
Q. And what was the average length of follow-up between the two groups?
A. The follow-up was anywhere from two to four years, I think.
Q. You think? Have you done any kind of write-up or written analysis?
A. No. It's not -- it's not published. I didn't write it up. I just sort of, you know, sat at the computer and pulled charts and pulled out the implant logs and sort of looked at this.
Q. Do you know what percentage of patients had been lost to follow-up?

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A. No, I don't. I mean, it wasn't -- again, it wasn't something I was trying to publish, so it wasn't a very rigorous analysis.

MR. FAES: So I would just state to counsel that if Dr. Roth is going to base his opinion based on this chart review, we would request to be provided with the basis for his opinions.

BY MR. FAES:

Q. Doctor, I just want to follow up briefly on something that you said regarding the TVT retropubic device.

You said that you're mainly using the TVT retropubic mechanically-cut mesh right now because of a cost issue; did I hear that correctly?

A. Yes.

Q. What cost issue are you referring to specifically?

A. My understanding is that the TVT-Exact is a bit more expensive, at least at our facility, than the older TVT retropubic.

Q. So you know that the TVT-Exact is offered in laser-cut mesh only; it's not offered --

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A. Correct.

Q. -- with a mechanically-cut mesh option, correct?

A. Correct.

Q. What about the -- just the regular TVT retropubic laser-cut; is there some reason why you don't use that as opposed to the mechanically-cut TVT retropubic?

A. I think we've, you know, we've had the mechanically-cut. I don't know the specifics of the contract pricing, but I've been told, you know, to try to limit costs, and we've continued to use the mechanically-cut TVT retropubic.

And I've continued to use the TVT-O, which is mostly mechanically-cut, as well, as opposed to the Abbrevo.

Q. If the TVT-Exact device were the same price as the TVT mechanically-cut retropubic device that you use currently, would you switch to the TVT-Exact device?

A. Not necessarily.

Q. So if you wouldn't switch to the TVT-Exact device if it was the same price as the TVT-R

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mechanically-cut, why did you say that you were primarily using the mechanically-cut mesh TVT-R right now because of a cost issue?

A. I'm sorry. I missed the -- can you repeat that?

Q. Sure. I guess I'm a little confused, Doctor.

You first said that you were using the mechanically-cut mesh TVT-R because of a cost issue, but then you said that you wouldn't necessarily switch to the TVT-Exact, which is a laser-cut, if it were the same price as the TVT retropubic mechanically-cut. So why did you say --

A. So you're asking -- you're asking why -- I'm sorry to interrupt. You're asking why I favor the retropubic TVT versus the TVT-Exact?

Q. No, I'm not. I'm asking why did you say -- why did you state earlier that you were primarily using the mechanically-cut mesh TVT retropubic because of a cost issue?

MS. KATZ GERSTEL: Object.

A. I still think that you're asking why I would favor the regular retropubic TVT if it were the same cost as the laser-cut Exact, and I

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would favor the regular TVT because I actually favor the handles more so and the trocars more than the TVT-Exact.

BY MR. FAES:

Q. So you'd agree then it's not necessarily the mesh in the TVT retropubic mechanically-cut that you favor over the TVT-Exact?

A. I would agree that -- well, for one there is the cost issue, but the other is I'm pretty comfortable with the original trocar passage and the handles. So I favor that product over the Exact.

Q. Do you believe that the safety profile for the TVT-O mechanically-cut mesh is identical to the safety profile for the TVT laser -- strike that.

Do you believe that the safety profile for the TVT-O mechanically-cut mesh is identical to the safety profile for the TVT-O laser-cut mesh?

A. Again, I don't think that I've seen scientific literature to say that -- that there's a difference or that there is not a difference. I've always used the mechanically-cut TVT-O.

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I've used the Abbrevo a handful of times. I have not seen a difference between laser-cut and mechanically-cut transobturator passage of the mesh.
Q. But again, you'd agree that with regard to the TVT-O, there's been no randomized controlled study specifically looking at the safety profile of the TVT-O mechanically-cut mesh to the TVT-O laser-cut mesh, correct?
A. To the best of my recollection, I've not found a randomized controlled trial to -- that compares the two, no.
Q. So again, like the TVT, your opinion that the safety profile of the TVT-O mechanically-cut is identical to the TVT-O laser-cut is based on your personal experience?
MS. KATZ GERSTEL: Objection.
A. Again, I don't know that I can say that they are equivalent. I have more experience with the mechanically-cut TVT-O than with the Abbrevo, even though I was -- you know, I had used the Abbrevo, and was a proctor for the Abbrevo. I haven't seen any sort of clinical

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difference in the patients that I've, you know, taken care of.
BY MR. FAES:
Q. Have you done a retrospective review of the TVT-O like you have for the TVT product?
A. I haven't.
Q. Have you done any kind of formal analysis with regard to the safety profile of the TVT-O mechanically-cut versus laser-cut mesh in your own patients like you have for the TVT product?
A. No. The -- the Abbrevo -- again, it's another sort of cost issue. The Abbrevo is significantly more expensive than the regular TVT-O, and I also prefer how the original TVT-O handles versus the Abbrevo.
So I've -- I don't think I have enough patients to really sort of come up with a Gestalt as to safety and efficacy because I just -- my preference is just to use the TVT-O mechanically-cut.
Q. Well, you understand that when I'm asking about the differences between the TVT-O mechanically-cut and the TVT-O laser-cut, I'm

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specifically talking about the TVT-O, not the -- I'm not including the Abbrevo.
A. I see. Okay.
Q. You understand that?
A. Okay. So, no, I mean, I -- I haven't, you know, sort of gone back and looked at any of that. I've been very happy with the mechanically-cut TVT-O product.
Q. Do you know how many -- excluding the Abbrevo, do you know how many -- approximately how many TVT-O laser-cut products you've used during the course of your career as opposed to TVT-O mechanically-cut?
A. I don't.
I think at one point the rep from the company brought in the laser-cut TVT-Os to try. This is years ago. He's no longer my rep. And my recollection is that it was -- they were more expensive than the mechanically-cut TVT-O. They handled similarly, so I just stuck with the mechanically-cut TVT-O.
Q. So do you recall what rep it was that first brought in the TVT-O laser-cut mesh for you to

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evaluate?
A. That was probably Kendall Bremner.
Q. When did that occur?
A. I -- I really have no recollection. He hasn't been my rep for -- for many years.
Q. And your recollection was after evaluating, that it -- the mesh of the TVT-O laser-cut handled similarly but handled a little bit differently than the TVT-O mechanically-cut; is that accurate?
MS. KATZ GERSTEL: Object to form.
A. I don't think it handled differently at all. I think it was sort of the cost issue again. They handled similarly, and it seemed like outcomes were the same when I followed those patients out. So there wasn't really a reason to switch or to change, especially when it was a little more expensive.
BY MR. FAES:
Q. Well, you keep saying that they handled similarly, correct?
A. Intraoperatively, yes.
Q. You'd agree that similarly is not the same as identically, right?

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A. Then I would say that they handled identically.
Q. So you're changing your testimony to state that you believe the TVT-O laser-cut mesh and the TVT mechanically-cut mesh handled identically; is that accurate?
MS. KATZ GERSTEL: Objection. Argumentative.
A. The -- in my hands -- and again, this has been years since I've used the laser-cut TVT-O. I don't know that I -- it's hard for me to sort of distinguish between, you know, similarly and identically. Identically is very strong, you know, language. You know, things that are identical are exactly identical, and I don't know that, you know, every sling case that I do is identical and every way that I put a sling in is identical. I put a sling in someone in a similar fashion to putting a sling in someone else. The way I tension slings is similar, but it's not always identical. So it's hard for me to say that they handle identically.
Q. Fair enough, Doctor.

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Now, on your report, again, it's combined with TVT and TVT-O, and I think we've established that you do intend to offer opinions with regard to both the laser-cut and the mechanically-cut configurations for both of those products, correct?
A. Yes.
Q. Is there any reason why on the title of this report you didn't state that your general report was for TVT-O mechanically-cut, TVT-O laser-cut, TVT-O mechanically-cut and TVT-O laser-cut as opposed to just TVT and TVT-O?
MS. KATZ GERSTEL: Objection.
A. I didn't realize the title needed to be all that detailed, I guess.
BY MR. FAES:
Q. But you'd agree that this expert report that you are offering opinions on, that you are offering opinions on four distinctly different products with distinctly different order codes all within the same report, correct?
MS. KATZ GERSTEL: Objection. Mischaracterization.
A. I mean, I'm prepared to offer opinions about

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the TVT line of products, both laser-cut and mechanically-cut.
BY MR. FAES:
Q. So you're prepared to offer opinions regarding the entire TVT line of products now, including the Abbrevo, the Secur and the TVT-Exact?
MS. KATZ GERSTEL: Objection.
A. Well, I wouldn't say the TVT-Secur, although I have a sense of experience with that. We're talking about the TVT and the TVT-O.
The fact that they're boxed differently, the fact that there's an L on the laser-cut box versus the mechanically-cut box, the fact that, you know, J & J makes a distinction between the products, clinically they have similar efficacy and handling characteristics and safety profiles. So I'm prepared to offer opinions about TVT and TVT-O laser-cut and mechanically-cut.
BY MR. FAES:
Q. But just to be clear for the record, you're -- you are offering opinions regarding four distinctly different products with four distinct order codes, correct?

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MS. KATZ GERSTEL: Objection.
A. Again, I'm -- I'm not subject or familiar with the order codes or all of that. I know that the laser-cut products have L on the box. We are talking about laser-cut TVT versus mechanically-cut TVT and TVT-O mechanically-cut and TVT-O laser-cut, and I'm prepared to offer opinions about those.
BY MR. FAES:
Q. Are you offering an opinion in this case regarding the TVT clear mesh and also the TVT blue mesh?
A. I mean, I don't really distinguish between the original TVT, which was not blue, and subsequent iterations of the TVT, which were then made blue, so yes.
Q. So you feel that the safety profile of the TVT clear mesh is identical to the safety profile of the TVT blue mesh?
A. If you're referring to -- when you say clear mesh, the TVT that was released before they decided to dye it blue, then yes.
Q. Do you know whether Ethicon and Johnson & Johnson issued a report -- well, strike that.

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Let me back up.
First of all, do you know when Ethicon and Johnson & Johnson first started offering the TVT retropubic in a blue mesh as opposed to a clear mesh?
A. I don't recall.
Q. Do you know whether or not Ethicon and Johnson & Johnson issued a report prior to releasing the TVT mesh in blue stating that -- or concluding that the change in the mesh from clear to blue represented a potential change that could affect the safety and efficacy of the device?
MS. KATZ GERSTEL: Object to form.
A. I'm -- I'm not aware of that communication.
BY MR. FAES:
Q. If assuming that to be true, that Ethicon and Johnson & Johnson concluded that a change in the TVT mesh from clear to blue was a change that could affect the safety and efficacy of the device, would that change any of your opinions in this case as to whether or not the safety profile of the TVT and clear mesh is identical to the TVT blue mesh?

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MS. KATZ GERSTEL: Object to form.
A. I guess I'd have to find some medical literature to, you know, support a difference in the clear mesh versus the blue mesh.
BY MR. FAES:
Q. But you'd agree, at least as to this point, you haven't specifically looked at the literature with regard to the question of whether the safety profile of the TVT clear mesh is different from the safety profile of the TVT blue mesh, correct?
MS. KATZ GERSTEL: Object to form.
A. I'm not aware of scientific literature differentiating between the clear mesh and the blue mesh in terms of safety, efficacy, adverse events.
BY MR. FAES:
Q. But my question is, have you, as an expert for Ethicon and Johnson & Johnson, specifically looked at that question?
MS. KATZ GERSTEL: Objection.
A. I've looked at the medical literature, and I -- to the best of my knowledge, I've not seen medical literature, scientific

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literature, you know, elaborating the difference between the clear and the blue mesh in terms of the safety, adverse events, or efficacy.
BY MR. FAES:
Q. So if you haven't seen any medical literature on that point, what are you basing your opinion on that the safety and efficacy of the TVT clear mesh and blue mesh is the same?
MS. KATZ GERSTEL: Objection.
A. My experience with the clear and the blue mesh.
BY MR. FAES:
Q. So you believe that you have personal experience with the TVT clear mesh?
A. I seem to remember that the -- there were TVT with clear mesh early on, but again, it's -- it's been years probably since I've seen clear TVT mesh. Maybe 2003, 2004 the mesh was clear, but I -- it's been a long time.
Q. Have you ever seen a TVT-O clear mesh, or has that mesh always been blue when you've used it?
A. I think that mesh has always been blue.

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Q. Okay. The expert report that's in front of you as -- in front of you marked as Exhibit No. 2, how much time would you say you spent actually writing that report as opposed to reviewing materials?
A. Hard to say. I mean, I would be reviewing and writing and then we were, you know, doing a lot of editing, as well. Maybe 25 hours, 30 hours of writing and editing and -- as opposed to just pure, you know, reading and reviewing written materials for the report.
Q. And how many hours would you say that you spent in reviewing materials for your report?
A. You know, I would say at least 50 hours. There were scads of articles, you know, to -- to review.
Q. How much time did you spend preparing for your deposition today?
A. Fifteen hours maybe.
Q. And that 15 hours would be at your preparation rate of $600 an hour; is that accurate?
A. Yes.
Q. And have you billed for that time yet?
A. I have not.

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Q. Okay. So that time is not included in the exhibit marked as 1-A that's in front of you, correct?
A. No.
Q. Is the expert report marked as Exhibit No. 2 in front of you, does that contain a complete and accurate reflection of all the opinions that you intend to offer in this case?
A. In regards to TVT and TVT-O, yes.
Q. Doctor, I'm going to hand you what's been marked as Exhibit No. 3 to your deposition.
(Deposition Exhibit No. 3 was marked for identification.)
BY MR. FAES:
Q. And can you tell me what Exhibit No. 3 is?
A. This is the General Reliance List.
MR. FAES: And I'm just going to ask counsel, because in the flurry of all the supplemental reliance lists -- is this his most updated one, or was there a supplemental one that I haven't got?
MS. KATZ GERSTEL: Supplemental.
MR. FAES: There is a supplemental one that I have got.

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Do you mind if I mark this?
MS. KATZ GERSTEL: No, go ahead. It's your copy.
MR. FAES: Oh, it's for me.
Does he have one for him that I can mark?
MS. KATZ GERSTEL: Mm-hmm.
MR. FAES: Doctor, what's your first reliance list marked at? I forget.
THE WITNESS: This is 3.
MR. FAES: Three? So I'll mark your supplemental reliance list as Exhibit 3-A.
(Deposition Exhibit No. 3-A was marked for identification.)
MR. FAES: Might as well just throw that out.
BY MR. FAES:
Q. Doctor, is Exhibit 3-A a comprehensive list of all of the materials you've reviewed and relied upon in forming your opinions in this case?
A. I mean, there are a few things on here that I did not specifically review, but I really didn't read a lot of some of the expert reports on the back of the list. I was trying

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to focus on my own opinions. But the bibliography here, the list of articles, is consistent with what I've used to generate my reports.
Q. What -- which of the expert reports on the back page have you not reviewed?
A. I didn't -- I haven't reviewed Jerry Blaivas's TVT-O report. I've reviewed some of Rosenzweig's reports when I first started generating my report. I did not review Bob Shull's Prolift report. I don't think that I reviewed Margolis's TVT-O report or Elliott's reports.
Q. You don't think you've reviewed any of Dr. Elliott's reports --
A. No.
Q. -- that deal with the TVT, TVT General --
A. No.
Q. -- or the TVT-O Gen?
A. No.
Q. Who prepared the document in front of you marked as Exhibit 3-A, which is titled Supplemental General Reliance List?
A. I mean, some of this is, you know, the medical

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literature from my reports, and so part of it I've -- I've helped prepare as, you know, references for my report, and I think that a lot of this is also from -- from -- from the attorney.
Q. Had you seen your supplemental reliance list marked as Exhibit 3-A in front of you prior to this morning?
A. Not this actual piece of paper, but I mean, I have on my computer a ton of articles and, you know, J & J documents. And so, I mean, I think this is consistent with, you know, everything, you know, all the databases that I have on my computer; but I haven't seen this physically in front of me.
Q. Have you seen it -- just to be clear for the record, have you seen it -- this document marked as Exhibit 3-A, your supplemental reliance list in front of you, in any form, whether physically or electronically, prior to this morning?
A. I mean, like I said, I've seen all of the names and all of the articles, you know, sequentially on a -- in the computer file, but

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not collected in a list form.
Q. So you'd agree that you didn't give final approval to the document marked as Exhibit No. 3-A in front of you that you confirmed that you'd reviewed all of the materials on this list prior to it being submitted; is that accurate?
MS. KATZ GERSTEL: Objection.
A. I did not give final approval, no.
BY MR. FAES:
Q. Doctor, what percentage of your practice is spent treating women as opposed to men?
A. 99.9 percent. I have had to treat two men in the last 12 years because I was one of only a few people doing a procedure called InterStim in the state, and, you know, the anatomy of the back is similar in a man or a woman. So I've had to treat a couple of men with InterStim. But other than that, it's all women.
Q. Doctor, I'm going to mark your CV as Exhibit No. 4 and hand that to you.
(Deposition Exhibit No. 4 was marked for identification.)

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BY MR. FAES:
Q. And this is your current CV, is that correct, or at least as of August of 2016?
A. Yeah, August of 2016.
Q. Your CV has a number of publications and presentations listed.
Are there any clinical studies that you're working on currently that aren't listed on your list of publications or presentations?
A. I mean, I submitted an abstract to the ICS meeting that's going to be in the fall, but I wouldn't call it a clinical study. It's more a report, not a clinical study.
Q. So it's kind of like the ND Posters that you presented at the ICS meetings in Beijing in 2012; is that accurate?
A. Well, I mean, it was their choice for them to not be, you know, non-discussion poster presentations. We'll see what ICS, you know, does with my -- with my abstract. It will probably be another poster at the meeting. So --
Q. So it's --
A. There's oral posters and there's

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non-discussion posters. The non-discussion posters are literally posters that hang in a hall. They're still accepted, but you don't get up in front of your colleagues and, you know, do a formal presentation.
Q. So what is the -- what is the subject matter of the presentation or poster that you've submitted for the upcoming ICS meeting?
A. It's the use of InterStim sacral neuromodulation in a woman with something called paradoxical puborectalis syndrome. It's defecatory dysfunction, chronic anal rectal pain. And she had failed multiple conservative therapies, and so we used InterStim in her, and she had a pretty dramatic response.
Q. So you'd agree that you're not currently working on any clinical studies involving pelvic mesh, correct?
A. That's correct.
Q. And this is a similar but different question.
You're not -- you'd agree that you aren't currently doing any current research on any polypropylene meshes; is that correct?

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A. No.
Q. Have you ever written any articles or publications specifically on the Burch procedure, either the open Burch or the laparoscopic Burch procedure?
A. Not specifically on Burch procedures and -- but I did write a paper years ago about voiding and outlet obstruction after anti-incontinence surgery, and my recollection is that maybe -- I'd have to go back and look, but it might have been that some of those patients did have Burches, but it's been 14 years.
Q. You're referring to the --
A. Delayed voiding and outlet obstruction after anti-incontinence surgery.
Q. Okay. Have you ever written a -- written or done research specifically on the autologous fascial sling?
A. No research and no reports on that.
Q. Do you consider yourself an academic physician?
A. I think that people who are in -- who are in teaching institutions would probably say that

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they are academic. I like to write some papers and occasionally do some teaching. So in that regard I'm quasi-academic.
Q. Yeah, that's actually about the answer I would expect from you. Usually I get a simple yes or no, but you're kind of unique in that you -- you're not -- you're not affiliated with any university or learning institution, right?
A. I'm not, no.
Q. But yet you still continue to regularly publish articles fairly regularly over the course of your career, right?
A. Yeah. It's fun.
Q. Would you agree that you don't hold yourself out as an expert in chemical engineering?
A. I'm not an expert in chemical engineering, no.
Q. Would you agree that you're not an expert in pathology?
A. Well, that's kind of a broad question. I'm not a pathologist, but I'm familiar with, you know, the pathology as it pertains to, you know, what I do, pathologic appearance of bladder epithelium, pathologic appearance of

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the vulva, pathologic appearance of, you know, ovaries. So I'm not a pathologist, but I'm familiar with the pathology of the disease processes that I deal with.
Q. You've explanted a number of different pelvic meshes in the course of your career, correct?
A. I have.
Q. Is it your normal practice to send any of those explanted materials out for pathology?
A. Every time.
Q. Would you agree that you're not an expert in polymer chemistry?
A. I am definitely not an expert in polymer chemistry.
Q. Would you agree that you're not a biomedical engineer?
A. I'm not.
Q. Would you agree that you've never done any bench research on polypropylene mesh?
A. I have not.
Q. Would you agree that you've not done any lab research on polypropylene mesh?
A. I have not.

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Q. Would you agree that you've never done any kind of pathological or pathology analysis on an explanted polypropylene mesh?
A. I have not.
Q. Would you agree that you're not a biomaterials specialist?
A. That's -- again, I sort of -- how do you define a biomaterials specialist? I'm -- I'm comfortable with the -- the meshes and the allografts and the autografts that I've used, but I'm certainly not employed in industry as someone who develops or manufactures biomaterials.
Q. Have you ever published any opinions -- published -- that polypropylene does not degrade in the human body?
A. I've published no opinions about polypropylene whatsoever.
Q. Have you ever -- well, I think you've already answered the next question, but I'm going to ask it anyway.
So you'd agree then that you've never published opinions that polypropylene does not create a foreign body reaction in the body?

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A. Yeah. I mean, I think I've answered that I haven't published anything on polypropylene in that regard.
Q. When were you -- when did you first implant a midurethral polypropylene sling?
A. 2003 or -- 2003 probably.
Q. And what was the first midurethral polypropylene sling that you implanted?
A. It was a retropubic TVT.
Q. And who trained you on how to put that in?
A. I think it was -- I think it was Neeraj Kohli, actually, back in 2003.
Q. And was that during a training seminar that was sponsored by Ethicon and Johnson & Johnson?
A. It was.
Q. When were you -- when did you first put the TVT-O device in for the first time?
A. I mean, let's see, I -- actually I put in TOTs I think in late -- in 2004 and TVT-O 2005, 2006. Good grief, I can't remember.
Q. And when you say TOTs in 2004, are you referring to the Monarc device or some other device?

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A. The Monarc.
Q. So you'd agree that the first transobturator midurethral sling that you were trained to put in was the Monarc device, not the TVT-O?
A. It was before the TVT-O was, so yes.
Q. And when you -- after you were trained to put in the Ethicon TVT-O, did you switch exclusively to the Ethicon TVT-O or did you continue to use the Monarc device as well?
A. So my experience with the Monarc device, the outside-to-in TOT, to be honest, I didn't really care for it very much, and so I used it a handful of times, went back to doing retropubic TVT. And then I was approached by J & J with their TVT-O, and I used that and actually was quite enamored with it.
Q. So other than the TVT retropubic -- the Ethicon TVT retropubic, the Ethicon TVT-O retropubic and the Monarc, you've also put in TVT-Securs before, right?
A. I've put in -- in terms of J & J products, yeah, I've put in the TVT-Secur and the Abbrevo.
Q. Have you ever put in a TVT-Exact?

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A. I have.
Q. You're not -- you're currently still a preceptor for the TVT and TVT-O, correct?
A. I mean, I haven't signed or updated a contract with J & J in a while. As far as I know, I am.
We currently don't have a rep, and I think the last event that I did was 2014. So if they wanted me to teach someone to do slings, I'd be happy to.
Q. You've been a preceptor for the TVT Abbrevo, correct?
A. I think technically I probably was a preceptor for the TVT Abbrevo, and I did train a physician in the northern part of our state to do Abbrevo. But I don't think it was they actively had me teaching people to do Abbrevos. It was more of TVTs and TVT-Os.
Q. How many Abbrevos have you put in on patients?
A. Maybe 20.
Q. So even though you've only put in approximately 20 TVT Abbrevos, Ethicon has you going out and teaching other physicians how to put that device in?

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MS. KATZ GERSTEL: Objection.
BY MR. FAES:
Q. Is that accurate?
A. I mean, the technique for Abbrevo is very similar to the TVT-O. So I -- I guess they felt comfortable with me training people to do Abbrevos with my experience with TVT-O.
Q. Is the TVT Abbrevo available at Central Maine Medical Center where you work?
A. It is.
Q. But you said it's substantially more expensive than the TVT retropubic device?
A. Well, I don't know -- it's more -- it's certainly more expensive than the TVT-O, and my understanding is the TVT-O is more expensive than the retropubic TVT. So it's more expensive than retropubic TVT.
One of the -- one of the OB-GYNs in the other group, he likes the Abbrevo, so he uses it, but infrequently.
Q. Which physician is that?
A. His name is Jonathan Commons.
Q. Have you ever been a preceptor or trainer on the TVT-Exact device?

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A. I don't think that I've trained anyone on TVT-Exact, no.
Q. Have you -- you've been trained yourself on it though, correct, or not?
A. Yeah.
Q. Specifically on the Exact?
A. I mean, the Exact is not all that different than just the retropubic TVT. So I don't know that I -- I did a formal cadaver lab, or course. I think I just used TVT-Exact because I've been trained to do TVT retropubic.
Q. So you didn't have any kind of separate formalized training for the TVT before you put the TVT-Exact in for the first time, correct?
A. No.
Q. What would you say your sling of choice is right now for patients?
MS. KATZ GERSTEL: Objection.
A. Well, I mean, I go through an informed consent process with the patients, and we discuss, you know, retropubic approach and the obturator approach. I -- I favor TVT-Os, but some people, you know, opt for the retropubic. Some people like the idea of the obturator

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approach, but I think you have to, you know, tailor the sling to the individual patient.
BY MR. FAES:
Q. So you'd agree that all things being equal, you generally recommend to patients the TVT-O approach as opposed to the TVT, correct?
MS. KATZ GERSTEL: Objection.
A. I think that sort of I'm in the habit of not really recommending. I'm in the habit of sort of presenting them with different options and trying to do, you know, the best, you know, means of educating them about these choices and then not letting them make a sort of a bad decision. But I don't say that's the one you should have.
I say, you know, this is the retropubic. These are, you know, the upsides and downsides of that. This is the obturator approach, the ups and downsides, and, you know, sort of engage them in that -- in that discussion. But I don't -- I don't necessarily actively recommend -- I don't know that I've actively recommended anything to anyone. I really like them to be part of the decision-making.

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BY MR. FAES:
Q. What do you tell patients are the upsides and downsides of the TVT retropubic approach?
MS. KATZ GERSTEL: Objection.
A. So we have longer-term data for the TVT retropubic, and so I can give them some decent counseling about what their long-term success rate with that would be versus TVT-O where I think our -- the longest-term data with TVT-O is around seven years. Obviously, we have significantly longer data for the retropubic.
And then we talk about adverse events and complications, the passage of the trocar as being retropubic, so that may put them at greater risk of a bowel or bladder injury.
The -- depending upon again sort of, you know, what you read in terms of literature, patients may have a bit more voiding dysfunction, urgency after a retropubic TVT versus the TVT-O.
The TVT-O, they may have groin discomfort after the procedure, usually self-limited, but significantly less risk of bladder injury or bowel or great vessel injury in the pelvis.

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Some people debate whether transobturator slings are appropriate for patients with ISD and whether retropubic slings should be done versus obturator slings in the morbidly obese or in the elderly. I'm more likely to put in a retropubic sling in a 36-year-old and more likely to put a transobturator sling in an 86-year-old.
So there is, I think, a lot of things that sort of go into choice of sling and -- and route of the sling based on a lot of, you know, patient factors.
BY MR. FAES:
Q. So I think you've answered this question a little bit in talking about the TVT retropubic, but let me follow up with the same question.
What do you counsel patients -- strike that.
What do you tell patients -- when you're counseling them about slings, what do you tell them are the upsides and downsides of the TVT-O device?
MS. KATZ GERSTEL: Objection.

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A. So the risks of TVT-O, much like risks of the TVT retropubic, bleeding, infection, need for further surgery. With the TVT-O there is less of a risk of injuring their bowel or their bladder or their urethra with the -- with the TVT-O than with the retropubic. Groin pain pretty much occurs unilaterally in the TVT-O slings and much more rarely in retropubic TVTs, although sometimes they have suprapubic pain.
There's some debate about discomfort with intercourse, that that might be more common with transobturator slings than with retropubic slings. And then again, there is just the long-term data where we have seven years, but the seven-year data seems similar to the seven-year data, long-term data for retropubic TVT.
BY MR. FAES:
Q. Now, you mentioned in your answer regarding the upsides and downsides of the TVT retropubic device that you counsel patients that there is more data regarding the long-term success rate when you're talking

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about the TVT-R; is that correct?
A. That's correct.
Q. What do you tell patients the -- you believe the long-term success rate of the TVT retropubic is?
MS. KATZ GERSTEL: Objection.
A. I usually say something along the lines of 80 percent cure rate at ten years for sort of all-comers and 16 percent improved.
BY MR. FAES:
Q. Is one of the key pieces of data that you're relying on for the long-term success rate of the TVT retropubic device the Nelson 17-year study?
A. Yeah. I mean, it's a small -- a small population, but they, you know, were able to follow those patients out for 17 years.
Q. Is that something that you specifically discuss with patients, that there is a 17-year follow-up?
A. I think I don't really use the 17-year follow-up. I use ten years.
Q. And why is that? Why do you use ten years instead of the 17-year follow-up?

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A. I don't know. I think -- I think ten seems to stick better in their mind.
Q. I just want to follow up on this line of questioning before I forget and move on to something else.
So in addition to the TVT retropubic, the TVT-O, the TVT-S, the TVT Abbrevo, the TVT-Exact and the Monarc products, what other slings have you used in the course of your career for stress urinary incontinence?
A. I've actually used the Caldera product. I mean, I've done -- that's been -- I've put that into human beings. I've been to cadaver labs for the Boston Sci and the Bard products. And I also did a lab on the Coloplast products, but the only other sling that I've put into humans was the Caldera.
Q. Do you remember specifically what Caldera product you put in?
A. I think they call it a Desara sling, and it comes with different handles. So the appealing thing about that product is that it's -- you know, the mesh material can then be attached to different handles, so you can

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put it in, you know, in a retropubic or down to the vagina or inside-out or outside-in approach. So, you know, that's kind of appealing, but I found their -- their mesh to be -- their handling characteristics were -- it's a lot more stiff than the J & J products.
Q. How many of those have you put in?
A. Two.
Q. When was that?
A. Probably in the last two years. I put in two, and I followed the patients, and they did okay. I just -- I didn't like how the material handled intraoperatively, so I didn't continue putting them in.
Q. Have you ever put in a Sparc sling?
A. No.
Q. Okay. And just so the record's clear, you've gone to cadaver labs for Boston Scientific, Bard and Coloplast, but you've never actually placed any of their slings in live human patients; is that accurate?
A. I think that's correct, yeah.
Q. Is there any particular reason why after going to a cadaver lab for Boston Scientific and

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learning how to put in one of their slings that you chose not to use that sling in your practice?
A. Well, I think the issue with their product was that they don't have an inside-out obturator sling, and I favor that over outside-in. I'm not, you know, all boned up on their literature about efficacy and adverse events, and I don't specifically remember how their mesh handled, you know, with -- on the cadaver, but they -- they don't have an inside-out approach, so just, you know, I'm continuing to do, you know, TVT-Os in that regard.
Q. But you'd agree that nobody has an inside-out technique, other than Ethicon and Johnson & Johnson's TVT-O or Abbrevo, correct?
A. The Caldera product that I just mentioned. So sort of the appeal of that was that they have different handles so you can attach their mesh to a helical handle, which is similar to the helical handle on an TVT-O and pass that from inside to out. You could also use a different handle and do the passage outside-in or go

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retropubic, but their mesh handles differently.
Q. So the same question with regard to -- first of all, what Bard products were you trained on, the Align, the Ajust, all of the above?
A. I think I played with the Ajust.
Q. Just to help you out, the Ajust is the mini sling.
Does that refresh --
A. Yes.
Q. -- your recollection?
A. Yeah. And, you know, it was on the market, I think, for, like, six seconds. It didn't last very long.
And the Coloplast sling, I think that's their adjustable sling. It's the Aris maybe.
Q. And after evaluating the Bard Ajust sling, is there any reason why you chose not to perform that product anymore?
A. Well, I mean, I never performed it in a human. I just went to the lab.
Q. Oh, yeah. Sorry, bad question. Let me back up.
Is there any reason after evaluating the

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Ajust in a cadaver lab why you chose not to use that product in your patients?
A. I guess I just didn't feel the need to change. I didn't really see a benefit to using that product over the J & J products.
Q. And what about the Coloplast Aris; the same question with regard to that?
A. The same thing. I didn't care much for the means of introducing it into the -- into the patient, into the cadaver. And, again, I really didn't feel the need to change from what I'm currently using.
Q. How many TVT-Securs have you placed during the course of your career?
A. It's been a long time since I've put a Secur in someone. I've probably put in maybe 50 or 60 Securs. Probably the last time I put one in someone was in late 2007, 2008.
Q. Why did you stop using the TVT-Secur device in late 2007, 2008?
A. I think that my experience in following my patients up with the TVT-Secur, it didn't have the -- the durability and efficacy of the traditional three-incision slings. And I

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think that there was, you know, enough data by, you know, 2008 to sort of, you know -- that it wasn't comparable to the traditional slings in terms of outcomes. So I think that's why I stopped using it.
Q. How -- what percentage of your practice would you say is devoted to treating mesh complications?
A. When you say complications, are we including people who have failed previous slings or are you -- what complications do you -- do you mean?
Q. Yes. All mesh complications. What percentage of your practice would you say are -- is devoted to treating patients with mesh complications?
A. So I would say that, you know, maybe 40 percent of my practice is redo slings for failures and -- and then complications related to placement of the mesh or long-term, you know, complications of mesh procedures.
Q. And how many slings would you say you put in a year currently?
A. Between 100 and 120.

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Q. And how many sling excision or revision procedures would you say you perform in an average year?
A. At least 20, at least, if not more.
Q. And if I changed my question to ask about how many mesh revision or excision procedures you perform in an average year, what's that number?
A. We're talking about slings?
Q. No. Now I'm expanding the question to any type of mesh, including pelvic or prolapse mesh.
A. I think that that number has sort of decreased in the last few years because of less -- less products being on the market. I mean, it's March. I haven't -- I haven't done any mesh excisions or revisions for either sacrocolpopexy mesh or mesh kits in the last, you know, three-and-a-half months. I mean, I think at this point I probably do, you know, less -- less than ten a year just because I think there's less mesh being used perhaps.
MR. FAES: Sorry. Can you read back that last -- the last two sentences of that last

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part? I kind of zoned out. I didn't hear what he said.
(Previous question read back by The Reporter.)
BY MR. FAES:
Q. So in terms of sling procedures, you're putting in about 100 to 120 a year, and you're excising or revising approximately 20 or more a year; is that accurate?
A. The majority of the -- if you're asking if they're -- if they're all my patients, if they're all the same --
Q. I'm not asking if they're all your patients. I'm just asking in terms of the ratio, you'd agree that you're putting in about 100 to 120 midurethral polypropylene slings a year, and you're excising or revising 20 or more a year; is that -- that accurate?
A. Yeah. I mean, the -- the patients who are getting revisions and excisions are -- those are not patients that I put slings into. But, yes, those are accurate numbers.
Q. So in terms of your practice in slings, about 80 percent of it's putting them in and about

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20 percent is taking them out, right?
A. And then usually putting another sling in those 20 percent. Yeah, it's -- that's pretty much, you know, correct.
Q. Has it been your experience that frequently when a patient has a problem with a sling that requires excision or removal, that they frequently go to a doctor that's different than the one that has originally implanted it?
MS. KATZ GERSTEL: Object to form.
A. I think that what happens, at least in Maine, is that a lot of the doctors who put in slings are not comfortable removing slings, and -- but, I mean, I've seen patients who've had some sling complications, and they go back and they see their doctor who put the sling in, and then that doctor sends them to me to deal with the complication.
I know that a lot of folks, and it's supported in the medical literature, not everyone goes back to see their implanting, you know, surgeon. So I mean, it's -- it's hard to say.

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BY MR. FAES:
Q. So you'd agree that -- well, strike that.
So physicians that -- there are many physicians that are comfortable putting them in, and most of those physicians have been trained by a mesh manufacturer on how to put the slings in, which is part of the reason why they're comfortable pitting them in, correct?
MS. KATZ GERSTEL: Object to form.
A. I -- I mean, I don't -- I mean, I know most of that people that put in slings in the State of Maine. I -- I know who they are. I know their names. I don't know -- I don't know who trained them. They certainly could have been trained during residency. Some of them may have been trained at a course that's sponsored by a mesh manufacturer. I don't know the extent of their training.
I know certain physicians in the state that I trained, and so, you know, I know who I trained to put in slings, but I don't know everyone's training background.
BY MR. FAES:

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Q. As part of your training sessions that you do for Ethicon and Johnson & Johnson when you're a preceptor, do you -- when you're training physicians on how to put them in, do you also train physicians on how to excise or remove the sling if necessary during those sessions?
A. The problem with that is that you have limited time, and one of the things that I certainly would discuss with doctors who I was training is, you know -- or at least something that I was always taught in training was that if you can't handle your own complication, then, you know, you should consider maybe not doing that procedure. But there really wasn't a chance to, you know, go through, you know, how to remove a sling. And I think, you know, spend enough time on, you know, trying to get them comfortable with the anatomy and placement and sort of the pearls of doing it and tensioning the slings and dealing with sort of perioperative complications like what do you do with a patient who can't pee after a sling and how long do you wait before you go and revise a sling. But we didn't really go

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through, you know, how do you remove the sling in those training sessions.
Q. So I'm just going to reask it in a different way, because I'm not sure I quite understood the answer to my question --
A. Sorry.
Q. -- in that long answer.
You'd agree that during the training sessions that you give as a proctor for Ethicon and Johnson & Johnson, you don't spend any time during the training sessions instructing physicians specifically how to remove or excise a mesh device, if it becomes necessary, during the course of the patient's treatment and care, correct?
A. That's fair, yes.
MS. KATZ GERSTEL: Object to form.
BY MR. FAES:
Q. And what's -- we talked a little bit about your -- how you counsel patients regarding the differences between the TVT and the TVT-O.
What percentage of the slings that you put in would you say are TVT as opposed to TVT-O?

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A. I would say that probably 10 percent are retropubic TVT, and the remainder are TVT-O.
Q. And of the slings that you're putting in right now, 100 percent of both the TVTs and TVT-Os are the mechanically-cut version of those products, correct?
A. That's correct.
Q. Besides the TVT-O -- TVT mechanically-cut, the TVT-O mechanically-cut, and the TVT Abbrevo device, what other products -- what other sling products are currently available to you to use at Central Maine Medical Center?
A. I don't know. I mean, I don't know what they stock the shelves with. I know they stock the shelves with my products, because I'm probably the one that does the most slings at the hospital. I mean, I think we could probably get whatever sling we wanted, but I don't know that they stock Boston Sci's products, for instance, or Coloplast's products.
Q. Is Central Maine Medical Center the only hospital where you currently have privileges?
A. Yes.
Q. And you're currently a licensed physician in

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the State of Maine, right?
A. Correct.
Q. Are you currently licensed in any other states?
A. No.
Q. What other states have you been licensed in?
A. North Carolina and Mississippi.
Q. And when did your license in North Carolina become inactive?
A. Probably when I left North Carolina. Within a year or two of 2001, I would imagine.
Q. The same question with regard to Mississippi.
A. I left Old Miss in the fall of 2004. So I just left -- let my license expire. Probably 2004, 2005.
Q. Have you ever been subject to any disciplinary action by any medical board in any state where you've been licensed?
A. No.
Q. How did you end up in Maine -- Portland, Maine?
A. Well, what I like to tell people is that there was a job in the back of a medical journal. And there was. You know, I grew up in New

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Jersey, and my parents had a little place in upstate New York, so we were near the lakes and the mountains and all of that. And when my mentor at Old Miss had sort of said that there was nothing left he could, you know, teach me -- he was kind of being funny about it -- I was looking for jobs. And Portland seemed like a nice -- or Maine sounded like a nice place to come, and there was a job in the back of one of the journals for Central Maine.
And I'd never heard of Lewiston, Maine, before, and my first question was, how close are you to Portland? Because I'd heard of Portland. And it's pretty close, and I've been here for, I guess, just over 12 years. So far so good.
Q. When you performed the TVT -- Ethicon TVT retropubic device, do you do it under local or general anesthesia?
A. We typically do it under general with something called an LMA, laryngeal mask airway, most of the time.
Q. Have you ever done a TVT retropubic under local anesthesia?

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A. I've done it with local and sedation. My experience is that I think you have to choose your patients carefully to do sedation with local. I know that the original TVT was -- that was sort of one of the selling points, that you could do it under -- under local.

For whatever reason a lot of my patients are, how shall I say, high anxiety, and more difficult to keep them still for a procedure with sedation than local. So I just pretty much do them all under general.

Q. When you do do a TVT retropubic under local anesthesia, do you perform a cough test to check the tension in the tape?

A. I go through the motions of a cough test. The problem with that is that not everyone leaks when they're supine. So I mean, I think it gives you some estimation of tensioning, but I don't know that I would hang my hat on cough tests as a great marker for efficacy post-op.

Q. Do you have an understanding of whether or not the TVT retropubic procedure, as it was originally designed by the inventor, was designed to be performed under local

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anesthesia with a cough test?

A. Yes.

Q. You do have that understanding?

A. Correct.

Q. Do you have an understanding that there's a -- some studies have shown a greater than 15 percent difference between -- in efficacy rates between performing a TVT retropubic under local anesthesia with a cough test as opposed to general anesthesia?

MS. KATZ GERSTEL: Object to form.

A. I can't think of that particular study right now.

The other issue is that not everyone who gets a sling is just getting a sling. A lot of my patients are getting a sling and a prolapse repair at the same time. So I think that's also something else that necessitates general anesthetic.

BY MR. FAES:

Q. Would you agree that an efficacy difference of 15 percent between doing the procedure under local and doing it under general is significant?

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A. I guess it depends upon what you define as efficacy. I mean, I'm -- I'm not familiar with what paper you're referring to, but I guess I'd have to sort of know when you say efficacy, do you mean post operatively, you know, they have a subjective -- is it a subjective outcome that you're looking at or is this a measurable urodynamic outcome that you're looking at or pad counts, weighted pads.

Fifteen percent, you know, I don't know -- it's hard for me to say whether that's significant or not.

Q. If Ethicon and Johnson & Johnson had data showing that there was a 15 percent difference in objective cure rate with the TVT when done under local anesthesia with a cough test as opposed to general anesthesia, is that information as an implanting physician who uses the TVT retropubic that you would want to know?

MS. KATZ GERSTEL: Object to form.

A. I think I'd want to know it. If it's a question of ultimately would it change my

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practice of doing the majority of my slings under general anesthesia. Hard to know.

BY MR. FAES:

Q. Assuming that it were true that there was a 15 percent difference in the objective cure rates for doing it under local anesthesia with a cough test as opposed to general, is that something that you would feel obligated to pass on to your patients when doing informed consent so that they could make a choice regarding whether they want local or general anesthesia?

MS. KATZ GERSTEL: Object to form.

A. I would pass it along to my patients. But you also -- you also have to sort of know your -- know your patients. And I can -- I can tell you that being here for 12 years, when I've mentioned the idea of honestly doing a sling under local with sedation, most of my patients really baulk at that, and their -- their comment is, I just want to be put out so --

BY MR. FAES:

Q. Do you know what the pore size is of the Prolene mesh in the TVT and TVT-O devices?

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A. Greater than 75 microns.
Q. Do you know any more specifically than that the size of the pores in the TVT or TVT retropubic device?
A. Not off the top of my head.
Q. Do you know what the weight of the device is -- of the mesh is in the TVT and TVT-O devices?
A. I don't.
Q. Do you know why Ethicon and Johnson & Johnson calls the mesh in the TVT and TVT-O devices the old construction mesh?
MS. KATZ GERSTEL: Objection.
A. The old construction mesh? I've not heard that term used to describe the TVT mesh.
BY MR. FAES:
Q. Do you have an understanding of what the mesh that's used in the TVT and TVT-O was originally developed for?
A. I mean, my understanding of sort of mesh products being used in the vaginal space is that it was based on the hernia literature and outcomes from mesh used for hernia repair, and that there were, you know, other forms of mesh

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products trialed in the vaginal space. The majority of them were -- had very untoward outcomes, but I think that's why -- or that's sort of the movement of mesh in the vaginal space was based on hernia literature.
Q. Do you have an understanding of when the mesh that was -- that is used in the TVT and TVT-O was first used in the human body?
A. I mean, Prolene has been used in the human body since probably the '50s. I can't remember exactly when Prolene was, you know, weaved or knitted into a mesh and then put into the human body. I don't have an idea of that.
Q. Do you have an understanding of whether or not the mesh that's used in the TVT -- well, strike that.
Do you know whether or not the mesh that's used in TVT and TVT-O was specifically designed for the treatment of stress urinary incontinence?
A. I don't know that it was specifically designed for the treatment of stress urinary incontinence, but I know that other meshes and

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products were also trialed for stress urinary incontinence, and all of the products that are currently on the market, or were recently on the market but then withdrawn from the market, were all some form of polypropylene.
Q. Do you know whether or not the mesh that's used in the TVT and TVT-O device is actually the same mesh as the Prolene hernia mesh that was used introduced by Ethicon and Johnson & Johnson in 1974?
A. I don't know.
Q. So just to be clear, you don't know one way or the other, correct?
A. One way or the other what?
Q. Whether or not the mesh in the TVT and TVT-O is or is not the same as the original 1974 hernia mesh introduced by Ethicon and Johnson & Johnson?
A. I don't know if it's the same mesh, no.
MR. FAES: We've been going about two hours. Would this be a good time for a break?
MS. KATZ GERSTEL: It would be great. Thank you.
(Brief recess taken.)

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BY MR. FAES:
Q. Doctor, we're back on the record after a short break.
Are you ready to proceed?
A. Yes.
Q. Doctor, if I could have you look at your CV, which I believe is marked as Exhibit No. 4.
If you look on -- I don't know what page it is, but it's -- I think it's second to the last page where it states Speaker's Bureau.
Tell me when you're ready.
A. (Examining document) Speaker's Bureau, yes.
Q. You're currently on the Speaker's Bureau for Pfizer?
A. I am.
Q. And you're currently on the Speaker's Bureau for GSK, correct?
A. Yes.
Q. You're currently on the Speaker's Bureau for Allergan, correct?
A. Yes.
Q. And you're currently on the Speaker's Bureau for Shionogi, S-h-i-o-n-o-g-i; is that correct?

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A. Yes.
Q. And what products do you speak for for Pfizer?
A. Well, I'll just say that it's actually been years since I've given any presentations for those companies because they've kind of moved away from a lot of speaker programs. However, when I was speaking for Pfizer, it was Toviaz and Detrol.
Q. What about GSK; what products have you spoken for on their behalf?
A. Vesicare and Myrbetriq.
Q. Allergan?
A. Sanctura.
Q. And...
A. Shionogi.
Q. Shionogi?
A. They have a product called Osphena, O-s-p-h-e-n-a, Osphena.
Q. What's Osphena?
A. It is a type of drug called a SERM. It's a Selective Estrogen Receptor Modulator. It's used for dyspareunia and vaginal dryness, oral tablet.

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Q. When you've been on the Speaker's Bureau for these four companies in the past, you've been compensated for your time by those companies for speaking engagements that you were involved in, correct?
A. Yes.
Q. And I found an older version of your CV from 2012, and on that version of your CV, you had Ortho-McNeil also listed under Speaker's Bureau at that time?
A. Yeah. So that would have been Elmiron, E-l-m-i-r-o-n, Elmiron. That's a drug for interstitial cystitis.
Q. And Ortho-McNeil is a Johnson & Johnson company, correct?
A. I think that's correct, yeah.
Q. And when you -- and what years approximately did -- were you a consultant for Ortho-McNeil at the Johnson & Johnson company?
A. I don't know that I was a consultant. I mean, I spoke for them. Let's see, maybe it could have been 2006 through 2009 or '10. I don't remember.
Q. It's your testimony that you don't know

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whether or not you were a consultant for --
A. No.
Q. -- the Johnson & Johnson company, Ortho-McNeil?
A. I said that I wasn't a consultant, that I spoke for them. You asked what years I was involved with them, and I struggle to remember what years I was speaking for them.
Q. Did you have a consulting agreement with them that you signed when you were speaking for them?
A. I don't remember the wording on the contract.
Q. But whether it was a consulting agreement or a contract, you did have a contract with the Johnson & Johnson company, Ortho-McNeil when you were speaking for them from approximately 2006 to 2009, correct?
A. Yes.
Q. And that contract involved, among other things, the amount of your compensation for any speaking engagements that you did on their behalf, correct?
A. It would have, yes.
Q. And under surgical preceptor consultant on

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your CV, you list Ethicon Female Urology, correct?
A. Yes.
Q. And Medtronic, correct?
A. Yes.
Q. And the Medtronic device, you're a preceptor for their InterStim product, correct?
A. Correct.
Q. And you receive compensation from Ethicon and Johnson & Johnson and Medtronic for preceptoring events that you do on their behalf, correct?
A. Correct.
Q. And do you have -- strike that.
And you've been a preceptor with Ethicon and Johnson & Johnson since approximately 2006; is that accurate?
A. That's about -- I think that's about right, yeah.
Q. Do you recall when your first contract was that you signed with Ethicon and Johnson & Johnson?
A. It may have been 2006. I know the rep from 2006. It was probably 2006.

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Q. Do you recall whether or not that -- whether or not you had a contract in 2007 with Ethicon and Johnson & Johnson that was for up to $60,000?
MS. KATZ GERSTEL: Objection.
A. I'm -- are you asking whether I was compensated $60,000 in that year?
I don't understand your question. I'm sorry.
BY MR. FAES:
Q. No. I'm asking whether you had a contract with Ethicon and Johnson & Johnson in 2007 that provided for a maximum of $60,000 in compensation?
MS. KATZ GERSTEL: Objection.
A. I -- I don't remember the wording of the contract. I'm sorry.
BY MR. FAES:
Q. Now, in addition to Pfizer, GSK, Allergan and Shionogi, you've also received payments from Astellas Pharmaceuticals?
A. GSK is Astellas or Astellas was GSK.
Q. And you've received payments in the past from Covidien?

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A. Covidien. Not that I'm aware of.
Q. You don't recall receiving any payments within the last three years from Covidien?
A. I mean, Covidien has become -- Medtronic has, I think, purchased Covidien. I don't remember getting paid by Covidien.
Q. You've received payments within the last three years from Coloplast, correct?
A. Probably payments towards going to a lab but not being a proctor or a speaker for them.
Q. But the answer to my question is, yes, you have received some payments from Coloplast within the last three years, correct?
A. Yes.
Q. And Coloplast is another mesh manufacturer that makes, among other things, the RS device that you went to a cadaver lab on, correct?
A. Yes.
Q. And you've received payments within the last three years from Caldera, correct?
A. Not that I'm aware of.
Q. You've received payments within the last three years from American Medical Systems?
A. The last three years?

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Q. Well, let me broaden that. The last four years.
A. I remember going to Minneapolis for an AMS event in May of 2011 perhaps, but that's -- that's all I can remember.
Q. And you would have received reimbursement for travel expenses, which is a form of payment, for -- from American Medical Systems for going to that event, correct?
A. Yes.
Q. And American Medical Systems is a manufacturer of pelvic mesh devices and slings, correct?
A. They were, yeah.
Q. And you received payments within the last five years from Astora Women's Health?
A. Okay. So, right, AMS became Astora briefly. It's probably that I had dinner with their rep or something, and that may be what's showing up on whatever you've got there.
Q. So you would agree that you have received payments from Astora Women's Health within the last five years?
A. I don't think that I received a check from Astora, but I think that I had a steak with

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the rep.
Q. So is the answer to my question, yes, that you would have received a payment of some kind or reimbursement from -- or an in-kind payment from Astora Women's Health within the last five years?
A. A dinner, yes.
Q. Would you agree that you've received payments from Bayer Pharmaceuticals within the last five years?
A. I -- I don't know who that would be or what that would be for. So I don't have any recollection of Bayer Pharmaceuticals.
Q. Would you agree that you've received payments from AbbVie, A-b-b-v-i-e, within the last five years?
A. Oh, AbbVie. I've attended --
Q. Possibly, just to help you out, in connection with a product called Lupron?
A. Yeah, thank you. Yeah, I've attended some dinner events that were responded by AbbVie.
Q. And you've received payments within the last five years from Ferring Pharmaceuticals?
A. Do you have a product for them, too?

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Q. Well, just for now can you -- I don't. Can you tell me if you recall receiving a payment from them within the last four years?
A. I don't. I'm -- I'm sorry.
Q. Have you received payments within the last five years from OmniGuide, Inc.?
A. I -- I don't know what that is. I'm sorry.
Q. Have you received payments within the last five years from Noven Pharmaceuticals?
A. Not that I'm aware of.
Q. Have you received payments within the last five years from Smith & Nephew, Incorporated?
A. Had dinner with the rep.
Q. So is the answer to my question, yes, you received payments within the last five years from Smith & Nephew, Inc.?
A. In a matter of speaking. They paid for my dinner, so yes.
Q. And you've received payments within the last five years from Bio-Rad Laboratories?
A. I -- not that I'm aware of.
Q. And you've received payments within the last five years from Cooper Surgical, Incorporated?
A. No, not that I'm aware of. It sounds like

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I've made a lot of money, but I don't -- good grief.
Q. I'm going to hand you what has been marked as Exhibit No. 5 to your deposition.
(Deposition Exhibit No. 5 was marked for identification.)
BY MR. FAES:
Q. And this is a document called Dollars for Docs pulled off the ProPublica website.
Have you ever seen this document before?
A. (Examining document) I have not.
Q. This document indicates that you received 84 separate payments for a total of $16,450 from 15 different companies in 2015.
Do you see that?
A. On the front page, yes.
Q. Do you have any reason to dispute the accuracy of this report?
A. Again, I'm not familiar with this, and I don't know where they got the information from, so with -- I don't -- I can't testify to how accurate this is.
Q. Are you aware that you can go onto this website and dispute any payments that you feel

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are inaccurately reported on this website?
A. You're pointing it out to me for the first time. I've not heard of this website before.
Q. Can you turn to page 3 of 7 of this document? And specifically I want you to look at the second line from the bottom, October 29, 2015.
How much? 399 related to pelvic implants. What for? Gift from Caldera Medical, Inc.
Do you see that?
A. Yeah.
Q. Does that refresh your recollection as to whether or not you've actually received any payments from Caldera Medical in the last five years?
A. I don't remember receiving a gift. I know it hasn't -- it hasn't been that long, but I don't remember what that was. It would have been something to do with slings. It escapes me. Sorry.
Q. So did you receive a payment or payment in kind from Caldera Medical of $399 on October 29th of 2015 or not?
A. I -- I don't remember. That seems like an odd

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number to me, 399.
Q. Do you have any reason, as you sit here today, to dispute the accuracy of this report?
A. Only because I don't remember it, so that would be my reason to dispute that, but I -- this isn't ringing a bell for me.
MS. KATZ GERSTEL: I just want to place an objection to using this document. I don't know what the source of the information is or if it's been verified.
BY MR. FAES:
Q. Do you know whether or not there is actually a government website called CMS.gov that tracks the payments that doctors receive from medical and device companies?
A. I know that there is a website related to the so-called Sunshine Act. I've not visited that website, but it -- maybe you have.
Q. Do you know that you can go to the CMS websites and dispute any information that they have with regard to a particular physician?
A. I've had no reason to visit their website, but that's news to me.
Q. I'm going to hand you what's been marked as

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Exhibit 6 to your deposition, and this is actually a partial report from the CMS.gov website for you for the same year, 2015.

(Deposition Exhibit No. 6 was marked for identification.)

BY MR. FAES:

Q. Do you see that at the top of the page Ted M. Roth, your name?

A. Yes.

Q. And if you turn to the second page of this, this actually shows that you received two payments from Caldera Medical, Inc., for a total of $750.54 in 2015.

Do you see that?

A. Up at the top of the second page, yes.

Q. Does that refresh your recollection about whether you received any payments from Caldera Medical, Inc., in 2015?

A. I'd have to go -- I mean, this is news to me. I'd have to go look at my taxes from that year and see if that were the case. I don't remember being paid by Caldera.

Q. Well, you understand that this would also include any kind of expense reimbursement

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or in-kind payment?

A. I mean, I've eaten with the reps, so it's conceivable that that's what, you know, this dollar amount is reflecting.

Q. So you'd agree that it's possible that you did receive $750.54 from Caldera Medical in 2015, either in terms of payments or reimbursement for expenses; you just can't remember one way or another?

MS. KATZ GERSTEL: Objection.

A. I mean, I don't remember being handed a check by Caldera, but I remember eating with the rep. So I guess my answer is yes.

BY MR. FAES:

Q. And you also see that there is on the same page four payments from Smith & Nephew, Incorporated, for $218.83?

A. Yes.

Q. Is that -- actually, I think you stated that you did remember being paid by Smith & Nephew, so I have no further questions on that.

If you go back to page 5 or Exhibit No. 5, the first page? This indicates that you received a total of 84 separate payments

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in 2005, correct?

A. 2005?

Q. Or 2015. I apologize.

A. Yeah, it says 84 payments for 2015.

Q. If that's accurate, that would indicate that you received some kind of payment from a medical or device company nearly one out of every four days in 2015; is that accurate?

MS. KATZ GERSTEL: Objection.

A. I think that's -- that's correct math. It's surprising to me.

BY MR. FAES:

Q. I'm going to hand you what's been marked as Exhibit No. 7 to your deposition.

(Deposition Exhibit No. 7 was marked for identification.)

BY MR. FAES:

Q. And this is the ProPublica report for you for the year of 2014. I know it's a little difficult to follow, but you see the second line 2014 is in a different color, so this is the 2014 report.

Do you see that?

A. Yes.

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Q. And this indicates that in 2014 you received 65 different payments from pharmaceutical and medical device companies for a total $12,835, correct?

A. Yeah, that's what it says.

Q. And if you turn to the second page, it states that you received $8,619 for consulting in three separate payments.

Do you see that?

A. I do.

Q. And if you go down to drug and devices in 2014, it states that the product name for that $8,619 is other.

Do you see that?

A. I do.

Q. Do you have any idea what that would be referring to in 2014?

If it helps, you can turn to Page 3 of 6, and it indicates that that $3,938 actually came from Ethicon US, LLC.

Do you see that? And it was on May 9th of 2014.

A. Yes.

Q. Does that refresh your recollection of what

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that payment would be for?
A. I may have -- it's very possible that that was one of the Bangor proctorships that we did, and then we had to go back and do it again.
My guess is that that relates to two trips in a short amount of time that I had to do to Bangor to get a doctor trained on TVT-O.
MS. KATZ GERSTEL: The same objection to the Exhibit 7 that I made to Exhibit 5.
MR. FAES: What's the objection?
MS. KATZ GERSTEL: That I don't know this information, if it's been verified.
MR. FAES: Well, that's why I'm asking the doctor questions. I'm asking him to verify it.
A. Yeah. My guess is that those payments relate to, again, to two programs I did in Bangor in a short amount of time.
BY MR. FAES:
Q. As you sit here today, do you have any reason to dispute that you were paid $8,880.75 by Ethicon in 2014?
A. I don't know how accurate the numbers are, but I don't have a reason to dispute it at the

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same time.
Q. Well, those -- the actual amounts that you were paid by Ethicon, LLC, in 2014 would be reflected in any 1099s that you would have received from Ethicon and Johnson & Johnson for that year, correct?
A. Yeah. I think that's how it works.
Q. Can you turn to --
A. Do you have my 1099?
Q. -- Exhibit No. 1? Go back to Exhibit No. 1, and I'm going to have you look at page No. 5 of that.
A. Page 5? Okay.
Q. Mm-hmm. And specifically on page number 5, No. 11, one of the requests that we made for you to bring today was copies of Schedule C and Form 1099 of your tax records for the preceding five tax years, as well as any other documentation that reflects consulting and/or expert fees charged to defendants.
Do you see that?
A. I'm sorry, you said under 11?
Q. Mm-hmm.
A. I see letters I, J, K and L.

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Q. Page 5, paragraph 11.
A. You said Exhibit 1, correct?
Q. Yes.
A. Oh, okay. Well, as I answered earlier, this is the first time I'm seeing this -- the record or notice to take my deposition, and I think Diana earlier said that she only filed it yesterday, so...
Q. So you'd agree that you didn't bring any of the documents requested that are responsive to request No. 11 here with you today?
A. No.
MS. KATZ GERSTEL: I'm just going to object and say that counsel's filed a response to this notice.
BY MR. FAES:
Q. You'd agree that you haven't made any attempt to comply with the federal rules and attempt to see if you have any documents responsive to request No. 11 in your possession, correct?
MS. KATZ GERSTEL: Objection.
A. I'm pretty sure I have the documents at home, but again, this is the first I'm seeing this notice to take my deposition. So, no, I did

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not bring those documents today.
MR. FAES: Okay. We would request that those documents be provided to us within the next 30 days.
MS. KATZ GERSTEL: And I'm just going to say again that we filed a response to this notice.
MR. FAES: So is it your position that you don't have to produce the items in -- requested in request No. 11 to our notice?
MS. KATZ GERSTEL: I'm just going to reiterate that we have filed a response to this notice and to request No. 11.
MR. FAES: Go off the record for just a second.
(Off-the-record colloquy.)
BY MR. FAES:
Q. Doctor, we are back on the record after a short break.
Are you ready to proceed?
A. Sure. Yes.
Q. Doctor, earlier I think you agreed that you first became a consultant or preceptor for Ethicon and Johnson & Johnson in 2006?

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A. To the best of my recollection, yes.
Q. Do you know if you had a contract with Ethicon and Johnson & Johnson for every year beginning in 2006?
A. My recollection is that they would have me sign a contract every year.
Q. Okay. Well, I'll represent to you that we have gone through the documents provided by Ethicon and Johnson & Johnson. We've only been able to locate your contracts for the year 2009 and 2011.
MR. FAES: So I would make a request to counsel that we be provided with all of the other years of Dr. Roth's contracts.
BY MR. FAES:
Q. Doctor, I'm going to hand you what's been marked as Exhibit No. 8 to your deposition.
(Deposition Exhibit No. 8 was marked for identification.)
BY MR. FAES:
Q. And does this appear to be a contract with you dated April 30th of 2009?
A. It does.
Q. You can turn -- I know you're a newbie at

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this, but these are called Bates numbers down at the bottom, these ETH numbers. If you could turn to the page ending in 0278?
A. (Examining document) Yeah.
Q. And I realize the quality of the copy is terrible here, but does that appear to have been signed by you and by Ethicon?
A. I can definitely see where Ethicon signed something. I can't see anything that remotely resembles my really awful signature there, but it looks like a contract that was typical of Johnson & Johnson that I would have signed.
Q. Do you have any reason to dispute whether or not this was -- well, actually if you turn to the page 0277.
And it appears that -- there again, the quality is still bad, but it's a little bit better. It appears to have been signed by someone at Central Maine Medical Center?
A. Right.
Q. Do you have reason to dispute that this is -- whether or not this was the contract that you actually signed in April of 2009?
A. This looks like it.

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Q. And if that changes at any time during the course of my questioning, let me know.
Do you recall that there was some controversy between you and the institution regarding the signing of this particular contract?
MS. KATZ GERSTEL: Object to form.
A. I don't -- I'm not too sure what you mean by controversy. I think that my institution wanted to look into whatever liability they might, you know, be involved with me proctoring, but I don't know that there was controversy.
BY MR. FAES:
Q. Do you recall whether someone at your institution actually made a request to Ethicon and Johnson & Johnson that changes be made to this contract in order for you to be able to sign it?
A. Knowing my institution, I certainly would not be surprised by something like that, but I -- I don't remember the specifics.
Q. Do you recall if anybody at your institution expressed concerns that a contract like this

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might be construed as you getting sort of -- and he used the word -- kickbacks from Ethicon and Johnson & Johnson for using their products?
MS. KATZ GERSTEL: Object to form.
A. Not that I'm aware of.
BY MR. FAES:
Q. You're not aware of that?
A. I'm not aware of that communication or whatever you may be referring to.
Q. You can turn to the page labeled Exhibit A, and the ending Bates number on that is 0279.
A. Okay.
Q. And you can see that this particular contract in 2009 under section four calls for you to be paid $3,000 for each eight-hour day.
Do you see that?
A. Yes.
Q. Is that an accurate representation of the fees that you agreed to be paid by Ethicon and Johnson & Johnson for your services?
A. Yes.
Q. You can turn to the following page at the bottom, Section B. It states that this

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contract is for up to $33,000 a year.
Do you see that?
MS. KATZ GERSTEL: Object to form.
A. Payments for consulting should not exceed $33,000 per year, yes.
BY MR. FAES:
Q. So you'd agree that this contract that you signed in 2009 provides for you to be paid up to $33,000 from Ethicon and Johnson & Johnson as a consultant, correct?
MS. KATZ GERSTEL: Object to form.
A. Up to that amount, yes.
BY MR. FAES:
Q. If you could turn to the page ending in 0275?
A. 75.
Q. And I specifically want to ask you about a section in paragraph 12?
A. (Examining document) Twelve. Okay.
Q. Starting on the seventh line down, starting with the word it states -- with the word you it states: You shall not make any representation relating to companies' products or to companies' clinical outcomes unless such representations have been reviewed and

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approved in advance by a company.
Do you see that?
A. I do.
Q. Is that a clause in this contract that you agreed to when you signed the contract?
A. As far as I remember, yes.
Q. So you'd agree that according to the clause in this contract, if you felt that the safety or efficacy rates of the TVT or TVT-O products, for example, were different from what the company wanted you to communicate regarding the safety and efficacy rates, you would be prohibited from communicating those rates during your preceptoring opportunities per this contract, correct?
MS. KATZ GERSTEL: Objection.
A. As far as I could understand the language here, I would be -- I would not be able to make any representation or claims that had not been reviewed probably by J & J legal, so correct.
BY MR. FAES:
Q. If you can turn to the page of this contract ending in 0281. Strike that. It's actually

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0283 that I want you to look at.
And you see that there's an addendum to this contract?
A. (Examining document) Okay.
Q. Do you recall whether this was an addendum that someone from your institution at Central Maine Medical Center requested be made to the contract?
A. I don't remember the specifics, but it mentions Laird Covey, who was, I think at that point -- he's retired now -- president of the medical center, and this must have been something that they felt like they needed to put into my contract.
Q. Well, just to help you out, Doctor, and move things along, if you can turn to page ending in 0277, and that's actually -- that will actually show you the original section of 22-B. It actually starts on the previous page.
But I will represent to you that the portion that has been changed is that the sentence at the top of 0277, in conducting other activities, you will not take a position

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or represent interests that conflict with Ethicon's interest during the initial term or any extended term of this agreement, is actually the clause that your -- that was struck in this addendum.
Do you have any recollection of that being removed from your contract at the request of your institution?
A. I don't.
Q. Do you believe that that is an appropriate request of Ethicon and Johnson & Johnson to ask of their consultants, that in conducting other activities, you will not take a position or represent interests that conflict with Ethicon's interest during your initial term or any extended term of this agreement?
MS. KATZ GERSTEL: Objection.
A. I mean, I think it would be reasonable for my medical facility to ask the same thing of me, to not take a contrary interest or an interest contrary to -- to their benefit. So it stands to reason that Ethicon would take a similar stance.
BY MR. FAES:

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Q. So do you think it was unreasonable for your medical center, Central Maine Medical Center, to ask for that provision to be removed from your contract prior to you signing?
MS. KATZ GERSTEL: Objection.
A. I -- you know, I wasn't really privy to the decision-making regarding this contract, and I'm not too sure I can really, you know, comment on that.
BY MR. FAES:
Q. So it's your testimony that you weren't privy to the decision-making regarding this contract?
You don't recall anything in writing regarding -- taking place regarding this contract?
MS. KATZ GERSTEL: Object to form.
A. This is 2009, eight years ago. I really don't remember the specifics. I don't know what prompted this addendum. I -- I honestly don't remember.
BY MR. FAES:
Q. Do you recall whether or not anyone at your facility at Central Maine Medical Center also

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expressed a concern with regard to this contract that certain provisions of it might be construed that you would be unable to recommend a competitor's product, such as an AMS Sparc or Monarc or Boston Scientific sling, according to the terms of this contract?
MS. KATZ GERSTEL: Objection.
A. You know, I don't know. I mean, the fascinating thing is that the majority of proctors that I know for J & J were also proctors for competitors' products. I myself just, you know, stuck with J & J.
Personally I would be -- I would find it difficult to, you know, one week proctor someone on a J & J sling and the next week proctor them on an AMS sling and, you know, make any sort of claims about, you know, which one was better. But many of my colleagues work for multiple device companies and had no problem with that.
BY MR. FAES:
Q. Doctor, I'm going to hand you what's been marked as Exhibit No. 9 to your deposition.
(Deposition Exhibit No. 9 was marked for

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identification.)
BY MR. FAES:
Q. And looking at the top page of this, this appears to be an e-mail from you to a Steve Gauthier and James Hagen, dated Saturday, March 14th of 2009.
Do you see that?
A. (Examining document) Yes.
Q. And it appears that you would have been privy to this entire e-mail string, correct?
A. Well, my -- yeah. My name's on it, and -- wow. Okay.
Q. And who is Steve Gauthier?
A. He's someone who recently was asked to resign from CMMC. He was involved with contracts. I don't know what his -- whether he was an attorney or whether he was a high school -- I have no idea what his background was, but he was involved with contracts at one point.
Q. Who's James Hagen?
A. James Hagan was a former -- he ran the specialty -- I think he was specialty practices manager. I'm not too sure, you know, what his title was at the medical

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center. He's retired.
Q. So he was an employee of Central Maine Medical Center, correct?
A. He was.
Q. Who is Laird Covey?
A. Also retired. I think his title was president of Central Maine Medical Center.
Q. And who is Lisa Ledoux?
A. Lisa Ledoux is no longer working at CMMC. She was -- she was employed under James Hagen. She was managing director of surgical specialty practices.
Q. And if I could have you turn to the last page of this document, and it actually goes kind of in reverse chronological order. So I think we're looking at actually the first e-mail in the string because it goes backward.
And if you look there, there is an e-mail from Steve Gauthier dated 3/5 of 2009 where it goes to Lisa Ledoux. And he states: I have reviewed this agreement and have some concerns. I need to see whether we have any special language in Ted Roth's contract that would address his ability to retain comp aside

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from his traditional MD duties. Do you have a copy of his contract?
Do you see that?
A. (Examining document) Yes.
Q. And then above you see the reply, that his contract, meaning your contract, says that he can -- that he may earn outside compensation as long as he receives written permission from Jim. What we would like to suggest is that the contract be drafted between CMMC and Ethicon and that the money comes directly to us. Once we receive it, we can issue a teaching stipend to Dr. Roth that is cleaner for everyone.
Do you see that?
A. I see that.
Q. Do you recall whether that was actually what occurred under your contract that was signed in April of 2009?
Did the payments go to your institution and then they paid you, or did the payments go directly to you?
A. No, the payments went directly to me.
Q. If you turn to the page ending in 6016, you

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can see an e-mail from James S. Hagen, who is apparently the vice-president of Physician Practices at Central Maine Healthcare.
Do you see that?
A. Yeah.
Q. Do you know James Hagen?
A. I knew him. He's retired now.
Q. And is he -- is he a medical doctor?
A. James Hagen was not a medical doctor. He was not a clinician, no.
Q. What was James Hagan's role within Central Maine Medical Center?
A. Vice-president of physician practices.
Q. And you can see that on this date James Hagen writes: The contract as written pretty much looks like a kickback and has a host of things wrong, including it is unclear as to the value of services being paid for, specifically since the majority of the compensation is coming from duties being performed that are already part of Dr. Roth's duties.
Do you see that?
A. I do.
Q. Does this refresh your recollection as to

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whether personnel at Central Maine Medical Center felt that your consulting contract as initially written could potentially look like a kickback?
A. In, you know, eight years almost to the date, I don't remember the specific language of this. There's a lot of communication between these administrators, and I haven't seen my e-mail part of this thread yet, but...
Q. So do you recall responding to this and trying to defend this contract as not being an actual kickback as someone at -- as James Hagen at Central Medical Center felt?
A. Well, I'm sure that it's here someplace, because most people know me to be relatively vocal about my opinions. So I'm sure I responded at some point.
MS. KATZ GERSTEL: Could the doctor have a moment to read over this?
MR. FAES: Sure. Would now be a good time to take our lunch break, and we can come back?
MS. KATZ GERSTEL: Okay.
MR. FAES: Okay.

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(Lunch recess taken.)
BY MR. FAES:
Q. Doctor, we're back on the record after a lunch break.
Are you ready to proceed?
A. Yes.
Q. Before we took a break we were talking about an exhibit, which is an e-mail chain regarding your employment contract with Ethicon and Johnson & Johnson, correct?
A. Correct.
Q. What exhibit number is that?
A. Nine.
Q. So if you look at Exhibit No. 9, it appears that you reply on the first page of this and attempt to defend the contract stating that you -- I will provide you with my J & J employment contract ASAP. You will see that there are no kickbacks or sham, slash, under-the-table consulting payments occurring. I only get paid for these teaching obligations that were -- are outlined in the formal employment contract.
Do you see that?

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A. Yes.
Q. And further on in that same sentence you state that these products are FDA approved.
Do you see that?
A. Yes.
Q. What products are you referring to that you believe are FDA approved?
A. The -- I mean, at this point in 2009, we were doing slings for J & J, as well as Prolift.
Q. So you believe that the TVT and TVT-O are FDA approved?
A. As far as I know, yes.
Q. Do you understand that there is a difference between approval and clearance?
A. I think I used the terms interchangeably.
Q. So when you were a preceptor for Ethicon and Johnson & Johnson during your preceptoring sessions, were you telling other physicians that the TVT and TVT-O devices were FDA approved?
MS. KATZ GERSTEL: Object to form.
A. I was probably using that language, yes.
BY MR. FAES:
Q. No one at Ethicon and Johnson & Johnson ever

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told you that that was incorrect or may be a violation of the law to represent their products as FDA approved rather than FDA cleared?
MS. KATZ GERSTEL: Objection.
A. Not that I'm aware of. I guess I don't understand the difference between FDA clearance and FDA approval.
BY MR. FAES:
Q. Fair enough. And further down on the -- I think it's the second from the bottom paragraph you state: I've trained doctors who would ordinarily refer their patients, slash, their complications, to doctors in their own networks, EMMC and MMC, but because of relationships that I've built with them, when they come to CMMC for teaching, they send those patients to me.
Do you see that?
A. Mm-hmm.
Q. So one of the benefits of continuing to be a preceptor and training other physicians on the use of slings, such as the TVT and the TVT-O, is that when they have complications with

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their patients, a lot of those physicians would send their patients to you for treatment of those complications; is that accurate?
MS. KATZ GERSTEL: Objection.
A. I mean, they might send me their complications, yes.
BY MR. FAES:
Q. And that's an important part of your practice. In fact, that's -- 40 percent of your practice is redoing slings for failures, correct?
MS. KATZ GERSTEL: Objection.
A. Yes.
BY MR. FAES:
Q. So it just makes good business sense to continue to train other physicians as a proctor or preceptor for Ethicon and Johnson & Johnson, correct?
MS. KATZ GERSTEL: Objection.
A. I don't know whether it makes good business sense to continue to train physicians. I wasn't actively seeking their complications or their -- or their business. I think, you know, it's a small state, and we developed, you know, a rapport and relationships. And I

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think that's sort of, you know, what that -- what that comment in the e-mail was about.
I certainly was not looking to develop a mesh complication business.
BY MR. FAES:
Q. So you weren't necessarily looking to have those referrals, but you understood at that time in 2009 that that was something that was occurring because a lot of the physicians that you were training were referring their complications to you, correct?
A. Yeah. I mean, I've been in the state since 2005, and I was getting complications referred to me by physicians, you know, prior to 2009. I was getting failed incontinence procedures prior to 2009, whether those be Burch procedures or slings.
Q. I'm going to hand you what's been marked as Exhibit No. 10 to your deposition.
(Deposition Exhibit No. 10 was marked for identification.)
BY MR. FAES:
Q. And this is another contract between -- another consulting contract between you and

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Ethicon and Johnson & Johnson, dated February 1st of 2011; is that correct?
A. Yes.
Q. And if you turn to Exhibit B, page ending in 6960, is that your signature and date of January 6, 2011, there?
A. Yes.
Q. And if you can turn to page -- the page before that ending in 6959, under Section B you see again that this contract has a maximum value of $33,000 per year, correct?
MS. KATZ GERSTEL: Objection.
A. Yes.
BY MR. FAES:
Q. So again, this contract provides for you to be paid up to $33,000 a year by Ethicon and Johnson & Johnson for your consulting work with them, correct?
MS. KATZ GERSTEL: Objection.
A. Yes.
BY MR. FAES:
Q. And, Doctor, would you consider yourself an expert with regard to warnings for medical devices?

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A. Would I be -- I'm sorry -- an expert on warnings for medical devices in regards to how I counsel my patients regarding medical devices or an expert on what the FDA issued? I don't -- I don't know what you mean.
Q. Do you consider yourself an expert with regard to what warnings should be included in the IFU or Instructions For Use for a medical device?
A. I think I'm -- I would be -- I've never written an IFU, but I have written surgical textbooks, which are IFU-like in their extent. But I'm -- I guess I'm comfortable with the warnings in the IFUs as they pertain to TVT products.
Q. Do you have an understanding of what risk information medical device companies are required to put in their IFUs?
A. You mean by the FDA?
Q. Well, I just mean in general do you have an understanding of what risk information medical device companies are required to put in their IFUs?
A. I think it would be what reasonable physicians or implanters would need to know in order to

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not only counsel their patients but also to decide whether they wanted to use that product.
Q. Do you know what FDA standards govern what risk information medical device companies are required to put in their IFUs?
A. I don't.
Q. Do you know what industry standards govern what risk information companies are required to put in the IFUs?
A. I don't.
Q. Do you know what departments medical device -- of a medical device company are involved in creating the warnings and precaution section or the adverse reaction section of an IFU?
A. Not specifically, no.
Q. Do you -- have you ever read any testimony from Ethicon employees regarding what Ethicon's position is on what needs to be in an IFU with regard to risk information?
A. Not that I recall.
Q. I think you already answered this earlier, but it's correct that you have never drafted an IFU for a medical device or assisted in

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drafting an IFU for a medical device, correct?
A. That's correct.
Q. And is that answer the same with regard to a prescription drug?
A. I've not been involved with physician or patient prescribing information for prescription drugs, no.
Q. Would you agree that physicians should be made aware of all the significant safety risks associated with the product in the IFU or instructions for use?
MS. KATZ GERSTEL: Object to form.
A. Could you repeat the question? I'm sorry.
BY MR. FAES:
Q. Sure. Would you agree that physicians should be made aware of all of the significant safety risks associated with a medical device in the IFU or instructions for use for that product?
A. I think that physicians should avail themselves of that information. The question I guess is when you say make aware of, I think that's -- the onus is the physician's responsibility.

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Q. Yeah. My question is a little different than that.
A. Sorry.
Q. My question is: Would you agree that the -- that a physician should be made aware of the significant safety risks associated with a medical device in the IFU or instructions for use for that medical device?
A. Yes.
Q. Would you agree that the warnings and adverse reaction section of the TVT IFU should include all the significant risks and complications related to the use of the TVT or TVT-O?
MS. KATZ GERSTEL: Object to form.
A. I don't know. When you say -- when you say all, I think, you know, there are certain risks and complications that are known to physicians doing these surgeries. I don't know that you need an exhaustive list of every one of them for people who are -- are doing this.
BY MR. FAES:
Q. So you would disagree with the statement that the warnings and adverse reaction section of

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the TVT IFU should include all the significant risks and complications related to the use of that device?
A. I guess I'm just -- I have a difficulty with the use of the word all. That just sounds like an exhaustive list, and I don't know that it would make a difference. I mean, there are, you know, common -- commonly-known risks of midurethral slings that -- or any sort of anti-incontinence procedure that I don't know all need to be in the IFU.
Q. Okay. So you believe that the IFU for the TVT and TVT-O does not necessarily need to include all the significant risks associated with the use of that device?
A. That's correct.
Q. Do you intend -- well, strike that.
Do you consider yourself an expert on the design of medical devices?
A. Not in the sense where -- I've not designed a medical device, but I'm familiar with sort of the history of the sling. But I'm not a biomedical engineer.
Q. Are you going to offer any opinions in this

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case specifically regarding the design of the TVT or the TVT-O?
A. In regards to?
Q. Just the overall design.
A. No.
Q. You'd agree then -- well, strike that.
Do you know what the standard is that a manufacturer must follow in designing a mesh product like the TVT or TVT-O?
A. That sounds very broad to me. I'm not sure what you mean by the standard.
Q. So are you aware of any standards or standards that a manufacturer must follow in designing a mesh product like the TVT or the TVT-O?
MS. KATZ GERSTEL: Objection.
A. In -- I'm sorry. In regards -- in regards to animal testing, sterilization techniques, manufacturing techniques? I don't know what you mean by standard. I'm sorry.
BY MR. FAES:
Q. Okay. Do you know how a medical device company goes about designing a device like the TVT or TVT-O?
MS. KATZ GERSTEL: Object to form.

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A. I mean, I know a little bit about the history of the TVT and sort of the ideas behind it and sort of how that came to -- to being. I don't know the specifics of, you know, once that idea was in J & J's hands, how they then proceeded to do testing or set up manufacturing or things along those lines.
BY MR. FAES:
Q. You'd agree then you don't know what kind of experts are involved in designing a device like the TVT or TVT-O?
MS. KATZ GERSTEL: Object to form.
A. You said experts?
BY MR. FAES:
Q. Yes.
A. You mean expertise or I'm not --
Q. Would you agree that you don't know what kind of experts that Ethicon and Johnson & Johnson or a company like Ethicon and Johnson & Johnson would need to use or employ in designing a device like the TVT or TVT-O?
MS. KATZ GERSTEL: Object to form.
A. I mean, I could, you know, conjecture that

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they would need physicians, statisticians, animal lab support, people, you know, in the manufacturing end. I think, you know, those are the types of experts that they would need for the design and manufacture of a product like the TVT.
BY MR. FAES:
Q. So you prefaced your answer with, you could conjecture.
Would you agree that you don't actually know what experts are involved. You're merely making a conjecture; is what accurate?
A. I don't know who J & J or Ethicon employed to -- in the process of developing the TVT, but my -- my guess would be it would be multidisciplinary groups of people, clinicians, surgeons, animal lab folks, biomedical engineers, people in the sterilization and manufacturing to have a product like this.
Q. But again, you prefaced your answer with, you would guess. So you're not stating that you know. You're just making an educated guess or conjecture, correct?

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A. Correct.
Q. Do you know what a design history file is?
A. I do not.
Q. Did you review the design history file for the TVT or TVT-O?
A. No.
Q. Do you know what a design failure modes and effects analysis is?
A. No.
Q. Do you know what an application of failure modes and effects analysis is?
A. No.
Q. Since you don't know what a design failure modes effects analysis is or an application modes failure analysis is, you would agree that you wouldn't offer any opinions regarding either of those analyses with regard to the TVT or TVT-O, correct?
MS. KATZ GERSTEL: Object to form.
A. Correct.
BY MR. FAES:
Q. Do you know whether or not the warnings in the IFU or instructions for use for the TVT and TVT-O are part of the design failure modes

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effects analysis?
A. Since I don't know what the design failure effects and modes is, I don't know if the IFU was part of that.
Q. Have you ever reviewed or are you familiar with any of Ethicon's internal standard operating procedures related to the design of the medical -- of medical devices or specifically the TVT and TVT-O?
A. No.
Q. Have you ever designed a medical device yourself or helped design a medical device?
A. Nothing that went very far, no.
Q. So nothing that went very far.
What have you worked on?
A. I -- I had some ideas about a change in the introduction mechanism for the InterStim, but we didn't do anything with it, and I didn't -- I didn't really walk it up the flag pole, so to speak.
Q. Do you know how long it takes to get a medical device product to market?
A. I do not.
Q. Do you own any patents for the design of

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medical devices?
A. No.
Q. Are you familiar with industry standards that govern medical device design?
MS. KATZ GERSTEL: Object to form.
A. No.
BY MR. FAES:
Q. In your expert -- your report, you state that you've implanted about 1200 midurethral slings.
Approximately how many midurethral slings have you explanted or revised in your career?
A. Geez, anywhere from 100 to 200 maybe.
Q. So you believe that you've explanted or revised somewhere between 100 and 200 midurethral slings for stress urinary incontinence in the course of your career; is that accurate?
A. Yeah.
Q. Could you be any more specific than that?
Do you know if it's more than 150 or less than 150?
A. I -- it's not something I really keep track of. I'm sorry.

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Q. Doctor, if I could have you look at your expert report, which is marked as Exhibit No. 2, and if I could have you look specifically at page number 5 and the second paragraph from the bottom where you state: Midurethral sling operations have been the most extensively researched surgical treatment for SUI in women and have a good safety profile.

Do you see that?

A. (Examining document) Yes.

Q. So I understand that you're making that opinion regarding midurethral slings, that they've been the most extensively researched treatment for stress urinary incontinence in women and have a good safety profile.

Are you making that same opinion specifically about the TVT retropubic?

A. TVT retropubic would be amongst those sling operations, and yes.

Q. Do you believe that the TVT retropubic sling is the most extensively researched treatment for SUI in the world?

Is that an opinion that you intend to

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offer in this case?

A. I mean, I haven't counted up how many papers as it relates to TVT versus Sparc, but yes.

Q. So even though you haven't done an analysis of how many TVT studies or patients there have been related to Sparc, you're going to offer an opinion that it's the most extensively researched surgical treatment for SUI?

MS. KATZ GERSTEL: Object to form.

A. To the best my knowledge, the majority of the literature out there on midurethral slings relates to retropubic TVT, so yes.

BY MR. FAES:

Q. So in terms of -- when you say that it's the most extensively researched, are you stating that it's the most extensively researched in regard to number of patients, quality of data, length of data, or all of the above?

A. Number of studies, probably most patients, follow-up, all the above.

Q. So have you done an analysis of the number of patients that have been studied with regard to the TVT retropubic as compared to a sling such as the Sparc?

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A. I mean, I haven't counted up individual RCTs. The best data that we can go on are the systematic analyses and the meta-analyses, and unfortunately most of those group all midurethral slings in together regardless of manufacturer.

So I can't -- I can't give you a number of, you know, how many women have had retropubic TVTs, you know, how many randomized controlled trials -- specifically how many randomized controlled trials there are off the top of my head specifically for retropubic TVT.

But the best scientific literature in support of the midurethral slings are from -- not from randomized controlled trials but from meta-analyses and the systematic analyses or systematic analyses. And those group midurethral slings in together.

Q. And that's a good point, Doctor. In your -- further on in your report, you discuss a number of different meta-analyses and Cochrane analyses, including the Novara, Schimpf, Dean, Rehman and -- Rehman studies, correct?

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A. Yes.

Q. And those are all studies that include some TVT slings, but they include a number of other different slings as well; is that accurate?

A. That's correct.

Q. Now, in writing your report, you -- I mean, obviously you've got a reliance list of materials that you relied on.

But in writing your report, would you agree that you discussed the studies that you felt were most important and relevant to you forming your opinions in this case?

A. You mean by discussed, discussed them in my report or discussed them with the attorney?

Q. No. I'm not asking about anything you discussed with your attorney. I'm just asking would you agree that your expert report marked as Exhibit No. 2 discusses various articles and facts, correct?

A. It does.

Q. You'd agree that the articles and facts that you discuss in your expert report are those articles and facts that you felt were most important to you in forming your opinions and

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conclusions in this case, correct?
A. Yes.
Q. And you specifically reference four different meta-analyses, the Novara, Schimpf, Dean and Rehman studies, that -- and all four of those are regarding midurethral slings in general, not specifically the TVT, correct?
A. Well, on that page 7, yes, those are the references for -- for that chart from Nager's paper on midurethral slings.
Q. Yes. And, in fact, you've copied and pasted a portion of Nager's 2016 paper into your expert report on page 7, correct?
A. Yes.
Q. And Nager's 2016 paper specifically discusses the four aforementioned meta-analyses that we talked about, right?
A. Yeah. He used those meta-analyses to construct that -- that chart.
Q. And would you agree that all four of those meta-analyses include in their analysis slings other than the TVT, correct?
A. That's my recollection, yes.
Q. How did you account for the fact that there

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were multiple other midurethral slings in these studies in doing your analysis where you concluded that the TVT and -- when you reached your conclusions regarding the TVT and the TVT-O?
A. I'm sorry. Could you repeat that?
Q. I'm not sure I can, so I'll restate it.
A. Okay.
Q. In your conclusions regarding the TVT-O, you relied on Nager's 2016 paper, which included four meta-analyses, correct?
A. You said my conclusions about the TVT-O, so I -- I don't know that his -- his paper included, or at least those meta-analyses included, both retropubic, pubovaginal slings, as far as I can remember, also transobturator slings as well. But I don't know that I -- I based my specific conclusion about TVT-Os based on Nager's paper.
Q. So you didn't base any conclusions regarding the safety and efficacy of the TVT-O on Nager's 2016 paper that you've included in your expert report here?
MS. KATZ GERSTEL: Objection.

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A. Well, not his -- not his paper. His paper was sort of more of a -- a commentary review of sort of the state of midurethral slings, and I used this graph because it seemed like a nice summary of the data for midurethral slings versus other -- other methods of anti-incontinence surgery.
BY MR. FAES:
Q. Right. Nager's 2016 paper is actually an editorial, isn't it?
A. Right. It's commentary, yeah.
Q. In fact, the heading on the paper says Viewpoint, right?
A. Correct.
Q. So if you intend -- going back to page 5 of your report, you stated that you do intend to offer an opinion that the TVT operation is the most extensively researched surgical treatment for SUI in women.
Do you intend to offer an opinion in this case that the TVT-O is the most extensively surgical -- most extensively researched surgical treatment for SUI in women?
MS. KATZ GERSTEL: Object to form.

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A. I don't -- I'm not too sure what you're asking, but I don't know if there's as much data for the transobturator slings as there are for the retropubic slings. So I'm not sure what you're asking.
BY MR. FAES:
Q. Right. You'd agree that there can only be one device that can be the most extensively researched surgical treatment for SUI, right?
MS. KATZ GERSTEL: Objection.
A. Well, I mean, there can be one procedure that is most extensively studied under the heading of the midurethral slings; and then under that heading, yes, there could probably be only one device that could be the most extensively studied out of that group of procedures.
BY MR. FAES:
Q. And you believe that that's the TVT and not the TVT-O, right?
A. That's correct.
Q. So you'd agree that the TVT-O is not the most extensively studied device for the treatment of stress urinary incontinence, correct?
MS. KATZ GERSTEL: Objection.

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A. I would agree.
BY MR. FAES:
Q. And you make your opinion about the TVT device being the most extensively studied sling for the treatment of stress urinary incontinence despite not having done a formal analysis comparing the number of patients or the number of studies as it relates to the Sparc sling, correct?
MS. KATZ GERSTEL: Objection.
BY MR. FAES:
Q. Or compared to the Sparc sling.
A. I mean, again sort of off the top of my head, I can't tell you how many studies have been done on TVT versus Sparc, but my recollection is that there are more TVT studies than Sparc studies.
I think going back to -- if we go to page 8 of my report, which helps with my memory, TVT has been studied in more than 100 randomized controlled trials. TVT-O has been studied in more than 60 randomized controlled trials; and I think, you know, again off the top of my head, those -- that makes them, both

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TVT and TVT-O, the most extensively studied retropubic and obturator slings. But I can't tell you off the top of my head how many RCTs the AMS product had or off the top of my head how many, you know, RCTs Sparc had.
Q. Don't you need to know the number of Sparc RCTs in order to opine that there are more TVT slings -- TVT RCTs than Sparc RCTs?
MS. KATZ GERSTEL: Objection.
A. I don't think I need to know the actual number. Just -- I think I need to know that there's just more of them. I don't know if that makes any sense.
BY MR. FAES:
Q. Did you know the number at any point?
A. I don't know the actual number of Sparc RCTs or Monarc RCTs.
Q. Have you done any kind of analysis of the quality of the Monarc studies compared to the quality of the TVT studies?
MS. KATZ GERSTEL: Objection.
BY MR. FAES:
Q. Or strike that.
Have you done an analysis of the quality

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of the TVT studies as compared to the quality of the Sparc studies?
MS. KATZ GERSTEL: Objection.
A. I've not looked at Sparc studies head to head with TVT studies, but -- and again, what I've looked at are the systematic reviews and the meta-analyses. And other doctors have sort of looked at the strengths and the weaknesses of a lot of those studies and sort of, you know, put together the meta-analyses, and -- but I haven't put them head to head myself, no.
BY MR. FAES:
Q. So you're just -- when you're making your opinion that the quality of the TVT studies is better than the quality of the Sparc studies, you're not basing that on your own formal analysis; you're basing that on the analysis of other individuals; is that accurate?
MS. KATZ GERSTEL: Objection.
A. I'm basing that on people that are in academics that are much more expert on statistics and doing systematic reviews in meta-analyses than I am, so yes.
BY MR. FAES:

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Q. Have you done an analysis of the quality of the TVT-O studies compared to the quality of the Monarc studies that are out there?
MS. KATZ GERSTEL: Object to form.
A. Again, I'm relying my opinions on the -- not necessarily individual RCTs but the meta-analyses and the systematic reviews.
BY MR. FAES:
Q. At the bottom of page 6 of your report, you state that MUS, including the TVT and TVT-O, are taught in residency and fellowship programs throughout the United States and are the gold standard procedure for SUI. To state otherwise would not reflect the reality of surgical management of SUI today.
Do you see that?
A. Yes.
Q. Is that an opinion that you intend to offer in this case?
A. Yes.
Q. Do you know whether the Burch procedure is still offered in residency and fellowship programs throughout the United States today?
A. I mean, I haven't been in academic -- a

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teaching institution in 12 years. My best guess is that there may be people doing Burches in select patients, probably not as a primary procedure but as a -- perhaps a procedure where someone has had a sling; they had an untoward event with a sling; the sling was removed; the patient had recurrent stress incontinence; and the patient opted to proceed with another surgery for their stress incontinence; and they did a Burch instead of doing another -- another sling, either pubovaginal or mesh.

Q. So I'm not sure if that answers my question.
Do you know whether --

A. I don't, no. Sorry.

Q. So you've done no analysis of whether -- of how many institutions still teach the Burch procedure today?

A. I mean, I'm in contact with folks at Duke on occasion. I don't think that -- I'm not aware that they're doing Burches. I don't know anyone doing Burches at Old Miss. I don't think that they're very commonly performed at this time.

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Q. Have you ever performed a Burch procedure?

A. Absolutely.

Q. When's the last time you performed a Burch procedure?

A. 2001, 2002.

Q. Would you agree that the Burch procedure for the treatment of stress urinary incontinence is still within the standard of care today?

A. I would not criticize someone for doing a Burch procedure if that's what they had to offer the patient. So I think it's within the standard of care.

Q. Do you know whether or not Burch procedures for the treatment of stress urinary incontinence are actually on the rise within the last two years?

A. That I'm not aware of.

Q. Do you think that would be an important fact to know when you're talking about the reality of surgical management for stress urinary incontinence today in your report?
MS. KATZ GERSTEL: Object to form.

A. I mean, I think, you know, what's maybe more important is to know the data supporting the

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use of midurethral slings versus data for Burches. I think it's more important to know the inherent risks of slings versus Burches. I think that, you know, maybe there are certain doctors out there that are not comfortable performing midurethral slings, and they're doing Burches.

I think -- I don't know that there's a rise of Burch procedures would impact my -- my personal practice or my expert opinion on midurethral slings.

BY MR. FAES:

Q. Do you know whether or not the number of midurethral slings performed in the United States has actually gone down over the past couple years?

A. That I don't know. I can tell you that in my practice, not that it's a reflection of the US, I haven't seen a decrease in slings.

Q. Do you think that would be an important fact to know in stating your opinion regarding the reality of surgical management of stress urinary incontinence today?
MS. KATZ GERSTEL: Object to form.

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A. In regards to -- what was the word before management? You said --

BY MR. FAES:

Q. Do you think that -- I'll restate the entire question.

A. Sorry.

Q. Do you think it would be important to know whether or not the number of midurethral slings in the United States was actually on the decline in issuing your opinion regarding the reality of surgical management of SUI today?
MS. KATZ GERSTEL: Object to form.

A. Again, you know, I don't think that what doctors do in terms of whether they favor one surgery or another would affect the data that we have for midurethral slings.

So, you know, I think there's probably lots of factors that influence decision-making between whether to offer a patient a midurethral sling or a Burch procedure. One of those factors is probably the ongoing litigation; and, you know, that may be the factor for why there has been a decrease in

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slings, as you say, or an increase in Burches.
You know, I think we have to practice evidence-based medicine. I think we -- you know, patients come to see me for advice about, you know, their medical care. They don't come to ask me about, you know, legal matters, and I don't talk to them about necessarily, you know, legal matters.
So I think there's -- there's probably lots of factors that go into why doctors choose one procedure, you know, over other.
Q. Would you agree with me that the popularity or prevalence of a particular procedure isn't necessarily an indication of its safety or effectiveness?
MS. KATZ GERSTEL: Object to form.
A. I would agree that the popularity of a procedure, you know, certainly can be related to its efficacy and/or its safety. But the popularity of a procedure may have nothing to do with safety or efficacy. It may have to do with demand.
BY MR. FAES:
Q. And you state that the TVT and TVT-O are the

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gold standard procedure for SUI.
Do you mean that the -- specifically the TVT and the TVT-O are the gold standard, or do you mean that midurethral slings are the gold standard?
A. We're -- I'm sorry. Where did I -- where did I say that?
Q. The bottom of page 6 still. MUS, including TVT and TVT-O, are taught in residency and fellowship programs throughout the United States and are the gold standard procedure for SUI.
A. That's basically quoting Serati's article. That is what he put forth in his article, but I would agree with that.
Q. So that's an opinion that you intend to offer in this case to a reasonable degree of medical certainty?
A. Yes.
Q. And again, my question was: Are you offering the opinion that specifically the TVT and TVT-O are the gold standard procedure for SUI or that midurethral slings are the gold standard procedure for SUI?

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MS. KATZ GERSTEL: Object to form.
A. I think that the gold standard for anti-incontinence surgery currently is -- are midurethral slings, and of that classification the most studied, and in my read and my recollection, the best data supports TVT and TVT-O.
BY MR. FAES:
Q. So just to make -- I just want to be clear on what your opinions are.
You'd agree that there can only be one gold standard, right?
MS. KATZ GERSTEL: Object to form.
A. I mean, if we're going to say one gold standard, you know, if I can put it in perspective, there are probably at least 12 different ways to do a Burch procedure. There are probably even more ways to do pubovaginal slings. So, you know, to say that a Burch procedure is the gold standard, there's, you know, 12 different ways to do one. But only -- only one can be the gold standard.
There's probably 20 ways to do a pubovaginal sling, but only one can be the

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standard.
Midurethral slings, I feel, are the -- the gold standard, and out of the -- that family of midurethral slings, I think that TVT and TVT-O are -- again have the most -- the most data and the best outcomes.
If I had to choose one, the TVT versus the TVT-O, the gold standard, I would say the retropubic TVT, because it's been around longer, and we have even more data for that than the TVT-O.
BY MR. FAES:
Q. So do you believe that the Bard Align sling is the gold standard for stress urinary incontinence?
A. I can't tell you because I don't think it's been out -- I don't think it's even on the market anymore. And --
Q. I think you're thinking of the Ajust.
A. The Ajust.
Q. The Align is still on the market.
A. You know, I don't think that there's enough data to say that it is any better or any worse than TVT. It's a midurethral sling, so, you

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know, theoretically it should work in a more physiologic manner than a pubovaginal sling or a Burch procedure.

Midurethral slings are the gold standard for stress urinary incontinence treatment.

Q. Right. I guess what I'm getting at, Doctor, is are you saying that all -- any midurethral sling for the treatment of stress urinary incontinence is the gold standard, or are you just saying that specific ones are the gold standard?

So, example, I asked you about Align, and I'm not quite sure what your answer was, quite honestly, so let me ask you a different question.

Do you think that the Boston Scientific Advantage sling is the gold standard for stress urinary incontinence?

MS. KATZ GERSTEL: Object to form.

A. I think -- again, I don't know the data for that particular sling. I don't think that there's enough data to say that it is superior to TVT or TVT-O.

TVT and TVT-O have been around longer

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than the other slings. They have the most data.

But in terms of your three general choices for anti-incontinence surgery, we've got Burches, pubovaginal slings and midurethral slings. Midurethral slings are considered by most folks out there to be the gold standard operation for stress incontinence.

BY MR. FAES:

Q. So I'm going to ask it a little differently, because I'm not quite sure I still got an answer to my question.

Can you answer yes or no do you believe that the -- for example, the Boston Scientific Advantage sling is the gold standard treatment for stress urinary incontinence?

Can you answer that yes or no, or can you not answer?

A. I don't know enough about that product to say how good it is or whether -- or how effective it is or what their -- their particular adverse event profile is.

Q. So you'd agree that not all midurethral slings are the gold standard; you can't make that

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claim.

MS. KATZ GERSTEL: Object to form.

A. I think as a group they are the gold standard. I think there are certain slings that have been removed off the market that did not perform as well as traditional slings. For instance, the TVT-Secur or even the MiniArc by AMS.

I think that single-incision slings are midurethral slings, but I don't think they are the gold standard. So, no, not all midurethral slings are created equal and not all are the gold standard.

BY MR. FAES:

Q. Right. So you'd agree that not all midurethral slings are created equal and that many midurethral slings have different safety and efficacy profiles, correct?

MS. KATZ GERSTEL: Object to form.

A. Yes.

BY MR. FAES:

Q. Would you agree that it's difficult to consider something the gold standard if it's no longer being manufactured or sold anymore?

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MS. KATZ GERSTEL: Object to form.

A. I think whether industry decides to manufacture something or not doesn't really impact, you know, whatever outcomes data were there when it was in place. So I don't know that I can say that.

BY MR. FAES:

Q. So you don't have an opinion as to whether or not a product can still be considered the gold standard even if it's no longer being manufactured or sold?

MS. KATZ GERSTEL: Object to form.

A. That's correct.

BY MR. FAES:

Q. So when you say that something is the gold standard procedure for SUI, what exactly do you mean?

Do you mean that it's the most prevalent; that it's the highest quality? Or what specifically do you mean?

MS. KATZ GERSTEL: Object to form.

A. So in terms of what I mean by the gold standard, is -- or at least what Dr. Serati meant in his article about the gold standard,

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is that TVT and TVT-O have become the standard by which other slings are compared in terms of outcomes, in terms of the safety profile, in terms of adverse effects.
Q. So what do you mean when you say that MUS are the gold standard treatment for SUI?
A. Well, MUS, midurethral slings, including TVT and TVT-O, are thought to be the gold standard. This is what Serati wrote in -- in his paper. And again, what I said earlier was that not all midurethral slings are, you know, created equal. I don't disagree with what Serati said, but I think what he's referring to are traditional three-incision midurethral slings, TVT, TVT-O amongst those, not single-incision slings.
Q. So do you intend to offer an opinion in this case that midurethral slings are the gold standard procedure for SUI?
A. I am.
Q. And you make that opinion even though you stated earlier, for example, that you don't have enough information to determine whether or not, for example, the Boston Scientific

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Advantage sling is the gold standard or not?
MS. KATZ GERSTEL: Object to form.
A. I mean, based on again what -- what we consider to be the best data, which is from the meta-analyses and the systematic analyses, where they grouped, you know, different, you know, manufacturers of -- of slings in together, that's what I'm basing my opinion on.
BY MR. FAES:
Q. Would you agree that a lot of opinions and facts that you discuss in your report are regarding midurethral slings as a group and not necessarily the TVT-O by itself or the TVT by itself?
MS. KATZ GERSTEL: Object to form.
A. I mean, you know, again, taken individually randomized controlled trials are pretty good evidence, but better evidence is afforded by larger reviews, systematic reviews, meta-analyses.
BY MR. FAES:
Q. So looking at page 16 of your report, you've republished a portion of

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Dr. Nager's 2016 editorial on midurethral slings here; is that correct?
A. (Examining document) What part of --
Q. I'm talking about the table.
A. Oh, I mean page -- you said 16. I'm sorry. You mean 7?
Q. Seven.
A. Yes.
Q. There's actually no page number on this page; I don't know why.
A. Page 7, right.
Q. And this table has a summary of different results that favor midurethral slings and complications that favor a retropubic colpopexy -- laparoscopic colpopexy or pubovaginal sling, correct?
A. Yes.
Q. And when we're talking about open retropubic colpopexy, we're talking about a Burch, right, open Burch?
A. Open Burch -- yes, colpopexy is an open Burch, correct.
Q. Okay. So from here on out, I'll refer to that as an open Burch, because I don't like that

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word.
A. Yeah, it's too many syllables.
Q. So is this just information that you found helpful, or do you intend to offer an opinion in this case to a reasonable degree of medical certainty, for example, that the data favors midurethral slings with regard to overall cure rates?
A. In terms of sort of couching my opinions and sort of putting things into perspective, I think this is a nice summary of at least, you know, information that Dr. Nager gleaned from three or four, you know, meta-analyses and systematic reviews.
So, yes, I'm prepared to offer an opinion that midurethral slings are favored versus Burch procedures in a number of ways elaborated by this graph, this chart.
Q. So what about with regard to TVT, are you going to offer an opinion in this case that specifically the TVT retropubic has a better all -- better overall cure rate than the open Burch procedure?
A. Yes.

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Q. And what are you relying on to come to that conclusion?
A. I have to comb through some of the studies that I've looked at. Let's see, so the data from Hilton Ward was more of a, you know, randomized controlled trial, and basically they came to the conclusion that TVT was not inferior to the then gold standard, which was the Burch. And then -- but the majority of the systematic analysis and meta-analyses that I've reviewed, you know, take into consideration all midurethral slings.
Q. Well, first of all, the Ward Hilton study found that it was not inferior --
A. Correct.
Q. So that doesn't really support that the overall cure rates for midurethral slings are better than open Burch, correct?
A. It doesn't say that it's better, but you also have to look at follow-up and, you know, specifically, you know, how do they define cure rate? You know, was that based on, you know, objective data, subjective data, pad counts, so...

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Q. And --
A. I'm sorry. Go ahead.
Q. Were you done? I don't want to cut you off.
A. Go ahead.
Q. Well, most of the other data that you're relying on that states that the -- for the conclusion that the TVT, the overall cure rates for the TVT is superior to the open Burch are meta-analyses which include other TVT sling products, right?
A. Yeah. I don't know specifically that there was a meta-analysis or systematic analysis that just limited midurethral slings to J & J products.
Q. Right. So, for example, the Schimpf study, which is reference number 17 in this table which is cited multiple times, that included the TVT and the TVT-O, but it also included a number of other products, including the I-Stop, Monarc, TVT-Secur, MiniArc and something called the Safyre, S-a-f-y-r-e, sling, correct?
A. Yes.
Q. So in forming your -- in relying on that

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material in forming your conclusion that specifically the TVT and not the midurethral sling has a better overall cure rate than the open Burch, what methodology did you use to eliminate all those other slings in forming your conclusion regarding the TVT sling as opposed to midurethral slings in general?
MS. KATZ GERSTEL: Objection.
A. I don't think that you can take -- unfortunately you can't take a meta-analysis and dissect out, you know, the individual studies. I mean, you can look at the individual studies and -- and look at the sling versus the Burch, but I don't think you can take the end product, which is the meta-analysis, and then, you know, retroactively tease out how well the Burch did. You just have to look at those -- or excuse me -- or how well the J & J TVT did. You just have to look at those individual studies.
You know, the majority of -- at least in this section of my report, we used the

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information from the meta-analyses and the systematic reviews because that information is better than a randomized controlled trial with limited numbers, so...
BY MR. FAES:
Q. Right. So you'd agree that if, for example, in the Schimpf study you took out all of the other manufacturers' slings and just compared TVT retropubic to open Burch or all the studies involving TVT retropubic to open Burch, you might reach a different conclusion, correct?
MS. KATZ GERSTEL: Object to form.
A. I mean, that's possible.
BY MR. FAES:
Q. And the same question with regard to TVT-O. If you took out all the other slings out of the Schimpf study and compared just the TVT-O to the open Burch, you might reach a different conclusion with regard to overall cure rates and some of the other things that were measured in that study, right?
MS. KATZ GERSTEL: Object to form.
A. Again, you're -- you're taking out significant

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numbers of patients from a systematic review, slash, meta-analysis. So, you know, de facto, it certainly could affect the end conclusions.
BY MR. FAES:
Q. So what methodology did you use to determine that the conclusions in the Novara, Schimpf, Dean and Rehman studies were applicable to the TVT retropubic device?
MS. KATZ GERSTEL: Object to form.
A. Is the information in the -- in the Schimpf and the Novara meta-analyses systematic reviews are consistent with the individual data that I've seen in the randomized controlled trials for TVT and TVT-O. That's my methodology, is that, you know, you have limited numbers of patients in randomized controlled trials. When you take, you know, greater numbers and put them into the systematic analysis and then subsequent meta-analysis, the results are similar.
And then, you know, to take my own personal experience with the products and having done, like, 1200 of them, my experience is consistent with what's in -- in the

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literature.
BY MR. FAES:
Q. Earlier, Doctor, we were talking about -- kind of jumped ahead, and we were talking about your statement on page 8 of your report that TVT has been studied in more than a hundred randomized controlled trials, and TVT has been studied in more than 60 RCTs.
Do you remember that?
A. Yeah.
Q. Would you agree that none of the TVT randomized controlled -- TVT hundred randomized controlled studies had a primary endpoint of safety?
MS. KATZ GERSTEL: Object to form.
A. I mean, most of these trials -- most trials for incontinence procedures are not -- they're not powered for -- to show differences in safety. They're powered for differences in a primary outcome like incontinence.
BY MR. FAES:
Q. Right. So you'd agree that of the hundred randomized controlled trials for the TVT, zero of those trials had a primary endpoint of

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safety?
MS. KATZ GERSTEL: Object to form.
A. I can't recall any of those trials specifically randomizing patients for sling that the primary outcome was, as you said, safety, whatever that means.
BY MR. FAES:
Q. So the same is also true with regard to the TVT-O, correct?
A. As far as I know, correct, yes.
Q. Do you intend to offer an opinion in this case that the TVT and the TVT-O device are both safe and effective?
A. Yes.
Q. And you're offering those opinions to a reasonable degree of medical certainty, correct?
A. Yes.
Q. If you go to page 9 of your report, at the end of the first paragraph you write that over 80 percent of women are cured or have significant improvement in their symptoms with either retropubic or transobturator route MUS for up to five years after surgery. And

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again, the Ford article is cited.
Do you see that?
A. Yes.
Q. And you'd agree that the Ford article is actually the Cochrane analysis that includes many other slings, other than the TVT and TVT-O, correct?
A. Yes.
Q. So what do you believe the percentage of women with SUI who are cured or have significant improvement in their symptoms with the TVT is at five years?
MS. KATZ GERSTEL: Object to form.
A. Well, I mean, besides, you know, what I, you know, believe in the Cochrane review and what I've seen in individual randomized controlled trials with follow-up and all of this is consistent with my own experience, which is that I would say that 80 percent of women are cured, and I would venture to say that 16 percent are improved, you know, between that one- and five-year mark after surgery.
BY MR. FAES:
Q. The same question with regard to the TVT-O.

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What would you state is the percentage of women with SUI who are cured or have significant improvement in their symptoms with either -- symptoms with TVT-O, sorry, five years after surgery?
A. I would say it's -- it would be very similar. 80 percent cure rate, 16 percent improved. Again, it all depends upon how you define cure, whether that's subjective, objective, how you define improvement.
Q. You'd agree that that five-year cure/improvement rate is a very important metric or yardstick, if you will, in your opinion that the TVT and TVT-O device is effective for treating stress urinary incontinence, right?
MS. KATZ GERSTEL: Object to form.
A. I think that regardless of what anti-incontinence procedure you're looking at, you need to have long-term data for it. So, you know, five years to me is certainly more important than one year, not to -- not to, you know, put down one year's worth of data, but five year's worth of data is, to me, more

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significant and certainly more significant for my patients.
BY MR. FAES:
Q. What do you think is the most significant metric to you in issuing your opinion that the TVT and TVT-O is effective for the treatment of stress urinary incontinence?
MS. KATZ GERSTEL: Object to form.
A. I guess you have to sort of look at it in a couple of different ways. I think you need to look at it in terms of patient satisfaction. I think that's an important metric, whether the patient would, you know, recommend the procedure to her friends or relatives, family members.
And I think that in addition to just the -- the pure data of cure rate or, you know, pad counts and -- even or objective absence of stress incontinence on exam or in a urodynamic lab, I think you also have to look at the low rate of reoperation to look at, you know, success. But there's a very low of reoperation for recurrence of incontinence after midurethral slings.

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BY MR. FAES:
Q. So if I understand your testimony correctly, you think there are three important metrics in your opinion that the TVT is effect -- TVT and TVT-O is effective: Patient satisfaction, objective cure rates and reoperation rates; is that correct?
A. Low rate of --
MS. KATZ GERSTEL: Object to form.
A. Low rate of reoperation after having a midurethral sling for incontinence.
BY MR. FAES:
Q. So what do you believe the patient satisfaction rate is for the TVT sling?
MS. KATZ GERSTEL: Object to form.
A. I don't know that I administer a formal visual analog score for patient satisfaction, but I think people are generally very pleased with their outcomes.
BY MR. FAES:
Q. Is there anywhere in your expert report where you disclose an objective number that you believe is the patient satisfaction rate for the TVT sling?

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MS. KATZ GERSTEL: Object to form.
A. I know it's been studied in some of the literature that I've reviewed. I don't know that I specifically put that in the report.
BY MR. FAES:
Q. So how low would the patient satisfaction rate have to get with the TVT before you would change your opinion that it's effective for the treatment of stress urinary incontinence?
MS. KATZ GERSTEL: Object to form.
A. I guess it's a matter of how you measure patient satisfaction, in what -- in what realm, what arena, what scoring system. I -- you know, to be honest with you, I haven't thought about that because overwhelmingly I see patients come back thrilled with, you know, their results. And sort of the common thing that I hear is why did I wait so long to have this done.
I really don't see a lot of unhappy folks who -- who've had slings.
BY MR. FAES:
Q. So am I correct in that you can't state to any

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objective quantifiable standard for at what point patient satisfaction would be too low for you to still give the opinion that the TVT is effective for the treatment of stress urinary incontinence?

MS. KATZ GERSTEL: Objection.

A. Like I said, it's not something that I've had to consider. I think that if I, you know, started doing these procedures and I was seeing patients back who were unhappy, dissatisfied, then, you know, certainly I would -- I would reconsider why I was offering that procedure to patients, but I can't -- I don't have a number or a percentage off the top of my head that I can give you.

BY MR. FAES:

Q. What do you believe are the objective cure rates for the TVT at five years?

MS. KATZ GERSTEL: Object to form.

A. I mean, what I tell folks is that probably, you know, 80, 83 percent are cured at -- at, you know, five to seven years.

BY MR. FAES:

Q. What would the objective cure rate at five

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years have to drop to in order -- before you would reconsider your position that the TVT is effective for the treatment of stress urinary incontinence?

A. I don't know that I could -- I guess I would also have to know, you know, what the alternatives were for me to alter my practice to offer them something else.

You know, objective cure rates, I mean, that's very good; but oftentimes, you know, an objective cure rate doesn't really correlate with subjective cure rates and what the patient perceives and patient related outcomes.

So, you know, you can have someone who objectively is still leaking urine in your office, but when you ask them if they are perceiving that they're leaking urine, a lot of times they may not be, and they're quite happy.

So there's more -- you can't -- I don't know that I could sort of tease out, you know, just an objective cure rate or just a subjective cure rate or just reoperation rate.

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I think you have to look at the whole -- whole picture, not just one element.

Q. What do you believe are the reoperation rates for the TVT?

MS. KATZ GERSTEL: Object to form.

A. It's -- in my hands, it's pretty uncommon that I have to go and do a second anti-incontinence procedure on -- on someone. Of course, my practice is also skewed where I do see failures usually from other physicians putting slings in, and depending upon what their physical exam is like, what their anatomy is like, I may have to either remove the sling initially, let them heal, and then we consider another surgery, or we just go back in and I put a new sling in them.

So, I mean, again, in my hands it's a pretty low rate of reoperation for recurrent stress urinary incontinence. I can't give you a number.

BY MR. FAES:

Q. Yeah. I'm going to just reask the question, because I may have phrased it inelegantly, and I'll just start with the caveat that I'm not

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asking you necessarily about your personal experience.

My question is: What do you believe are the overall reoperation rates for the TVT as reported in the medical literature?

MS. KATZ GERSTEL: Object to form.

A. I don't -- I don't know that I can tell you off the top of my head. I don't know off the top of my head. I'd have to look through my report and see whether we even discuss that in the report.

BY MR. FAES:

Q. Am I correct in that you can't state any numerical quantitative standard to where the reoperation rates for the TVT would reach a level that would be unacceptable to you and you would change your opinion that they -- that the TVT is effective for the treatment of stress urinary incontinence?

MS. KATZ GERSTEL: Object to form.

A. Again, I can't really offer a number because it -- it's pretty uncommon that I have to reoperate on someone after they've had a sling.

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BY MR. FAES:
Q. What do you believe are the key metrics or measurements for your opinion that the TVT and TVT-O device is safe for the treatment of stress urinary incontinence?
MS. KATZ GERSTEL: Object to form.
A. My major metric is what's sort of published in the literature, which is a very low rate of severe adverse events. So a very low rate of death, low rate of pulmonary embolus, sepsis, bowel injury, great vessel injury. Things that are severe or life threatening.
BY MR. FAES:
Q. So do you consider the rates of non-life threatening but life-changing adverse events, such as chronic pelvic pain that lasts the lifetime of the patient or the inability to ever engage in sexual intercourse again in your analysis of whether or not the TVT and TVT-O device is safe?
MS. KATZ GERSTEL: Object to form.
A. In my experience, I've -- I've not seen patients have issues with chronic pelvic pain or inability to have intercourse after a sling

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that I've put in them.
With that being said, I've seen patients who had midurethral slings and were looking at all different brands of midurethral slings and different routes of passage come in with, as you said, life-altering issues, pain, fistula, malposition of the sling, et cetera, et cetera.
You know, I think that the data that I reviewed for the report shows that chronic pelvic pain is pretty uncommon after midurethral slings. I think that dyspareunia is pretty uncommon after midurethral slings. In fact, there's some data that suggests that sexual function improves after the placement of a midurethral sling.
But in regards to safety, I think that, you know, all procedures for incontinence, they all have very similar complication profiles; dyspareunia, chronic pelvic pain, erosion or exposure of material either into a viscus or into the vagina. These can all occur, not just with mesh procedures, but can occur with traditional procedures.

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Q. So in what percentage of patients with the adverse event after a TVT or TVT-O of never being able to comfortably engage in sexual intercourse for the rest of her life need to be seen before you would say to yourself this product or procedure is unacceptable to me; I don't believe it's safe?
MS. KATZ GERSTEL: Objection.
A. Yeah. I mean, it's -- that to me is a very hypothetical question, because I'm just not seeing those types of patients, so I -- I've not thought about that, you know. I can't give you a number.
BY MR. FAES:
Q. So if after treatment with a TVT or TVT-O it was found that 5 percent of patients were unable to comfortably engage in sexual intercourse for the rest of their life because of the TVT or TVT-O, would that change your opinion on whether or not it's safe and effective?
MS. KATZ GERSTEL: Objection.
A. Well, I mean, safe and effective, I mean -- what you just stated I don't think has

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anything to do with the efficacy.
BY MR. FAES:
Q. Fair enough.
A. I think, you know, there's -- there's more to it than, you know, what I offer the patient. It's -- the patient is part of the equation here. I think, you know, part of the informed consent process with a sling, in my mind, should involve a discussion about both, you know, the benefits, as well as the potential adverse events that can occur, complications, and what they may expect long term.
I think there are plenty of patients out there who, if you spoke with them and you said, if I do this procedure on you, you have a 5 percent chance lifetime of not being able to engage in comfortable intercourse again, but on the flip side you have a 90 percent cure rate, I think that, you know, there's going to be a lot of patients out there who are really bothered by urine incontinence who are going to still have this procedure for that 5 percent, five-women-out-of-one-hundred risk.

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Q. So you'd agree then that a 5 percent risk of never being able to engage in sexual intercourse comfortably for the rest of their life following a TVT or TVT-O isn't high enough to you to conclude that the device is not safe?
MS. KATZ GERSTEL: Objection.
A. You know, it sounds like we're -- we're gambling or we're playing poker with a number. I don't -- I don't have a number in mind. I don't -- I don't think about, you know, things, you know, with a specific, you know, number in mind.
In terms of whether to offer it to a patient or not, it's a procedure that I've been doing for well over a decade and, you know, I'm not -- I'm not seeing patients with debilitating complications or long-term sequela from the procedure.
You know, I don't -- I don't know what that number would be, but, you know, whatever number that would be it would be something I would discuss with my patients as part of, you know, the informed consent procedure and, you

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know, lay it on them.
Q. You stated that one of the key metrics to you in issuing your opinion that the TVT and TVT-O device is safe is a low rate of serious adverse events, and in defining serious adverse events, you're defining that as life-threatening events; is that correct?
A. That's how I would define a serious adverse event is something life threatening.
Q. So with that definition in mind, how high would the risk of serious adverse events with the TVT or TVT-O need to be in order for you to change your opinion that the TVT and TVT-O device is safe?
A. Again, you know, to put it in perspective, we're dealing with a surgery that is for a non-life-threatening condition. It's for a quality of life condition. And again, as -- I can't give you a number as to, you know, how many serious adverse events I would need to stop offering that to patients as a matter of ethics.
But when I do informed consent with a patient, I try to present them with as much of

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the risks and those rates of risk as I can, you know, muster. But I can't give you a specific number as to, you know, 15 percent -- what number -- what percentage of serious events, you know, I would stop offering this procedure to patients. I haven't thought about it, because it's not happening.
Q. Can you tell me how much higher the rate of serious adverse events, as you defined them, with regard to the TVT and TVT-O would need to be in comparison to a feasible alternative for the same indication before you would change your opinion that the TVT and TVT-O device is safe?
MS. KATZ GERSTEL: Objection.
A. I think what you're asking is for the same indication but also balanced with similar efficacy.
You know, we have pubovaginal slings. We have Burches. We have urethral bulking. We have midurethral slings. And we have physical therapy. And, you know, unfortunately they're not equally effective, and they all have their own unique set of risks and complications.

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You know, I -- I don't know what number that would be to get me to stop using midurethral slings because it's a very hypothetical, you know, question.
BY MR. FAES:
Q. Is there any device or surgery for the treatment of stress urinary incontinence that you believe is not safe or effective?
A. I think that, you know, in a particular surgeon's hands, you know, they can have very good outcomes with Burches and with a very low rate of adverse events, wound infections, transfusions, things like that. And the same thing goes towards pubovaginal slings. Midurethral slings the same thing.
Pelvic floor physical therapy doesn't involve surgery, but it may not be as effective as the other techniques, because it's like any other exercise program, what you put into it is, you know, sort of what you'll get out of it.
But I think that there are people out there that are very good at doing pubovaginal slings. The technique is similar but

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different than midurethral slings. And both of those are even more different than retropubics. And, you know, there's data to say that, you know, top down is not as good as bottom up for retropubics.

You know, I think in a particular surgeon's hands, you can have pretty good success with -- or pretty good safety with any of those.

Q. Would you agree with me that there isn't any specific medical device for the treatment of stress urinary incontinence that you can point to that you believe is unsafe?

MS. KATZ GERSTEL: Object to form.

A. Well, I think that there were some products on the market that were removed years ago, Protegen sling in particular, that was unsafe. Other than that, you know, overall anti-incontinence procedures are safe.

BY MR. FAES:

Q. So what specifically about the Protogen device led you to the conclusion that it was unsafe for stress urinary incontinence?

A. The Protogen device had a pretty high rate of

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both, as far as I can remember -- it's been years now -- vaginal as well as urethral erosion.

Q. So you would agree with me that a device like the TVT or TVT-O could have a high enough rate of vaginal and urethral erosion to where you would conclude that it was unsafe for the treatment of stress urinary incontinence?

MS. KATZ GERSTEL: Objection.

A. Again, that's a hypothetical question, because TVT and TVT-O don't have very high erosion rates or exposure rates at all.

I mean, you know, one of the reasons why I don't offer Burch procedures to most of my patients is because there is significant morbidity with a Burch.

So I guess I would agree with you that there is some threshold for, you know, safety. I don't know what that threshold, you know, would be for TVT, TVT-O. I never had the opportunity, thankfully, to use the Protogen sling, and I, off the top of my head, can't remember what their -- what the rate of exposure was or rate of injury was.

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BY MR. FAES:

Q. So you just anticipated my next question. You don't know, as you sit here today, the -- what the overall rate of exposure was for the Protogen sling with regard to vaginal and urethral erosions, correct?

MS. KATZ GERSTEL: Object to form.

A. Not off the top of my head.

BY MR. FAES:

Q. If the rate of vaginal and urethral erosions for a particular sling for the treatment of stress urinary incontinence were found to be 19 percent, would you -- would that be high enough for you to conclude that that device was not safe for the treatment of stress urinary incontinence?

MS. KATZ GERSTEL: Objection.

A. You know, that's hard to say. Are we asking 19 percent urethral erosion or 19 percent just vaginal exposure rate, combined?

BY MR. FAES:

Q. Combined.

A. You know, the other issue that I would need to sort of look at because unfortunately a lot of

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what's in the literature about urethral erosions is that it wasn't that the material eroded or poked -- poked through the urethra but that the -- the physician surgeon probably missed a urethral injury at the time of the implant. So a lot of, quote, unquote, erosions into the urethra were actually missed injuries.

You know, I don't know the -- I don't know that number. I can't -- I can't give you a number that would sway me from doing -- doing the procedure. If -- you know, I counsel my patients about those risks with -- with TVT and, you know, the rates of erosion or rather vaginal exposure are exceedingly low with TVT.

I can tell you that in my hands I don't think that I've ever seen someone that I put a TVT, a TVT-O into with a mesh exposure. That's 1200 patients. And that's consistent with the literature.

But it's also about patient selection. I don't put slings into certain individuals, smokers, poorly controlled diabetics.

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I'm getting a little wordy. I can't give you a specific number as to when I would quit doing slings on my patients.
Q. So you would agree with me that there's no objective numerical standard that you can point to with regard to the rate of vaginal and urethral erosions with a sling device for stress urinary incontinence to where you would conclude that that device is no longer safe for stress urinary incontinence?
MS. KATZ GERSTEL: Object to form.
A. Again, I guess the question is is how many -- you know, I would take a thousand vaginal mesh exposures over a single urethral exposure as complications. Because a lot of mesh exposures are asymptomatic and can be treated, you know, nonmedically -- or excuse me -- nonsurgically, medically.
So again, it's for me to give you a number, an objective number as to when I would, you know, stop doing slings because this is all very hypothetical, in my mind, because we're not seeing erosion rates of 19 percent with TVT, TVT-O.

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BY MR. FAES:
Q. We're not? You're not aware of any randomized controlled study that showed a 19 percent erosion rate with TVT?
MS. KATZ GERSTEL: Objection.
A. Not off the top of my head. That seems -- you're talking about a vaginal exposure or talking about urethral erosion?
BY MR. FAES:
Q. Talking about vaginal exposures and tape projections.
A. I'm not familiar with -- with that literature.
Q. If there were such a study, would that change your opinions in this case regarding the safety of the TVT sling?
MS. KATZ GERSTEL: Objection.
A. I would have to review the article and how it was done, patient selection, you know, at what point the surgeon was in their learning curve with the device. I think there's a lot of -- of factors involved with, you know, publishing a paper like that. I think you have to look at that. I mean, I would certainly look at that very carefully, but I wouldn't

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immediately be swayed away. I'd have to, you know, digest that paper.
BY MR. FAES:
Q. But I'll take it from your response that as you sit here today, you're not aware that at one point in 2013 Ethicon and Johnson & Johnson actually had data published on their website regarding a randomized controlled study comparing the TVT retropubic to the Sparc device which showed a 19 percent erosion rate with the TVT and a 6 percent erosion rate with the Sparc; you're not aware of that, correct?
MS. KATZ GERSTEL: Objection.
A. No, I'm not. I'm also not aware of that being published in the literature.
MR. FAES: Can we go off the record for a quick second?
(Brief recess taken.)
BY MR. FAES:
Q. Doctor, we're back on the record after a short break.
Are you ready to proceed?
A. Sure.

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Q. Before the break we were talking a little bit about safety rates and the Protogen sling.
I guess my question to you is this: You've offered an opinion in this case that the TVT and TVT-O device are safe, and you've stated that the only stress urinary device that you can point to that you feel is not safe is the Protogen, right?
MS. KATZ GERSTEL: Object to form.
A. I guess it depends upon how you define, you know, not safe. I mean, if -- medical errors can occur. A bowel can be injured with, you know, retropubic approaches because of, you know, how the trocar is angled, previous surgery. You could injure, you know, one of the vessels in the pelvis. I guess it depends on what you mean by not safe.
I mean, the Protogen kind of stands out because I think specifically it was removed for people claiming that it was not safe. Again, it's been years and -- since I even thought about the Protogen sling.
BY MR. FAES:
Q. So I guess my question to you is this: What

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objective standard are you applying for your conclusion that the TVT and TVT-O is safe for the treatment of stress urinary incontinence?

How would I know a device for stress urinary incontinence that isn't safe if I saw it?

MS. KATZ GERSTEL: Object to form.

A. You know, again, I guess it depends upon what you feel is a significant number of serious adverse events. You know, my review of the literature, my experience with TVT is that there is a very low rate of serious adverse events with that device. I can't -- I can't really offer you a number as to, you know, what -- what number, what percentage of procedures leading to a serious adverse event equates to, you know, that device not being, you know, safe. You know, I don't know.

When I think about it, you know, when you look at the MAUDE database, when you look at the numbers of what they -- what they call adverse events, some of them not very -- not very serious, but adverse events, you know, you know the numerator, but I don't know the

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denominator.

I can't -- I can't tell you what -- what that magic number is where I would -- I would stop offering a procedure for safety reasons.

BY MR. FAES:

Q. Doctor, if you turn to page 24 of your report, and on page 24, second paragraph down, you state that TVT is amongst the least stiff meshes available as an MUS, and you cite the Moalli article.

Do you see that?

A. Yeah.

Q. Now, do you know whether or not the Moalli article was specifically studying the mechanically-cut mesh or the laser-cut mesh?

A. I have to look back at it. I can't remember off top of my head.

Q. You would agree that based on the timing of the article, it's most likely the mechanically-cut mesh, correct?

A. Based on the article coming out in 2008, which means that her work was done way prior to that, it's most likely based on mechanically-cut mesh.

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Q. Do you remember that one of the conclusions of that article was also that the TVT mesh could easily deform under a minimal amount of tension?

MS. KATZ GERSTEL: Object to form.

A. I think it could deform, but the amount of -- my recollection is this was a uniaxial testing that she put the meshes through, but that amount of tension was -- although you say minimal, I think that the amount of tension to cause it to deform was supraphysiologic; that it was above and beyond, you know, what someone could manifest with a cough or a Valsalva or a squat.

BY MR. FAES:

Q. So if someone concluded that the TVT mechanically-cut mesh could deform under a minimal amount of tension, would you disagree with that conclusion?

MS. KATZ GERSTEL: Objection.

A. I guess the question is is whether that deformation is clinically relevant and whether it makes a clinical difference in efficacy and outcomes.

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BY MR. FAES:

Q. But my question is if someone gave the opinion that the TVT mesh could actually deform under a minimal amount of tension or a minimal amount of force, would you agree or disagree with that opinion?

MS. KATZ GERSTEL: Objection.

A. Would I change my opinion that it's the least stiff mesh?

BY MR. FAES:

Q. No, no, no. That's not what I'm asking.

A. I'm sorry.

Q. My question is if someone offered the opinion that the TVT mechanically-cut mesh can deform under a minimal amount of tension or force, would you agree or disagree with that statement?

DEFENSE COUNSEL: Objection.

A. I guess I would -- I would really need to know a minimal amount of force, what that means. I would need to know the process by which they're putting the mesh through that force. You know, is it an animal model? Is it bench-top model?

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I would need more information, I think.
BY MR. FAES:
Q. Have you ever engaged in the study of how much force a TVT sling is subjected to during an implantation?
A. How much -- you mean how much force I'm putting on it through -- when I'm placing it through the pelvis?
Q. Well, not you specifically, but in general have you ever engaged in the study of how much force a TVT sling is typically subjected to during implantation?
A. I've not read anything in regards to how much force is applied to the mesh during placement.
Q. So you would agree -- so you wouldn't offer any opinions in this case regarding whether the TVT mesh during implantation in the body is subjected to five newtons of force or ten newtons of force or 15; you have no number that you know of that the TVT is subjected to when it's implanted in the body or once it's in the body, correct?
MS. KATZ GERSTEL: Object to form.
A. I guess I'm a little bit confused if you're

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asking what the force on the sling is after it's been placed versus how much forces it may be seeing in the course of being placed. And, no, I can't -- I can't give you a specific number as to what -- how many newtons a cough is or a squat is.
But my recollection of the -- and I don't know that we quoted it here -- Dr. Dietz in Australia did a study of meshes looking at uniaxial tension or deformation of mesh, and I think the number he had was 10 to 15 newtons. But again, that's -- it's supraphysiologic in terms of, you know, what the mesh would see with a cough, a sneeze, going to the gym.
BY MR. FAES:
Q. Do you intend to offer any opinions in this case as to what percentage the TVT mesh can become elongated when subjected to normal forces during implantation of the mesh?
MS. KATZ GERSTEL: Object to form.
A. Again, I don't know how that would affect clinical outcomes. So I don't -- I don't know that I have an opinion about elongation of the mesh during implantation.

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BY MR. FAES:
Q. So you don't intend to offer any opinions in this case one way or the other as to how elongation or deformation of the mesh could affect clinical outcomes?
MS. KATZ GERSTEL: Object to form.
A. I'm sure that, you know, it certainly makes sense that if you put a sling on a significant amount of stretch, that you have ruined or changed the mechanical properties of the sling. It's not the same piece of material that you've -- that you started with. But clinically whatever forces or amount of elongation occurs in the placement of the sling does not affect clinical outcomes and that's what -- you know, what we have to look at.
BY MR. FAES:
Q. Would you agree that the TVT mesh is not designed to fray?
MS. KATZ GERSTEL: Object to form.
A. I mean, earlier I said that, you know, did not -- or I have not designed a biomedical device. I have not found that the TVT devices

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fray at all.
BY MR. FAES:
Q. Have you read any documents or any memorandums in this case from Ethicon medical directors where they conclude that fraying is actually inherent in the construction of the TVT mechanically-cut mesh?
MS. KATZ GERSTEL: Objection.
A. I think that if fraying occurs, I haven't seen that -- that affects clinical outcomes or efficacy.
BY MR. FAES:
Q. Would you agree that if fraying does occur, it would be considered an unwanted effect of the TVT mesh?
MS. KATZ GERSTEL: Objection.
A. Again, I don't know how clinically relevant fraying or not fraying is, because I don't see -- I don't see any sort of untoward effect on clinical outcomes if fraying occurs. I don't -- I don't know that it does.
BY MR. FAES:
Q. So you're unaware and you've never seen multiple reports from physicians to Ethicon

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and Johnson & Johnson where they report frayed edges of the mesh protruding through the vaginal epithelium of women that have been treated with the TVT sling?
MS. KATZ GERSTEL: Objection.
A. So I've read reports of mesh exposure, which I think is what you're describing.
BY MR. FAES:
Q. No. I am specifically describing frayed edges of mesh sticking through the vaginal epithelium reported by doctors to Ethicon and Johnson & Johnson.
MS. KATZ GERSTEL: Objection.
A. I guess I'm -- through -- through the incision that they placed the mesh through? Through a separate area?
BY MR. FAES:
Q. Through a separate area, not through the incision.
A. So that -- what you're saying is that that's a mesh exposure; that someone had the mesh implanted and then they re-presented to their doctor with an edge of the mesh coming through the vagina?

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Q. Right. An exposure which the physician who trimmed the mesh specifically described as a frayed edge; have you ever seen reports of that to Ethicon and Johnson & Johnson?
MS. KATZ GERSTEL: Objection.
A. I mean, what happens to the mesh when it's within the vagina, I think, is -- and, you know, what it's subjected to potentially, you know, toilet paper and intercourse and other sorts of external stimulus can certainly affect the appearance of mesh. I have not read reports of frayed edges on exposures. Exposed mesh is exposed mesh.
BY MR. FAES:
Q. So if you saw multiple reports from doctors where they reported to Ethicon and Johnson & Johnson seeing frayed edges of the mesh protruding through the vaginal epithelium or sharp, spiky edges, would that change your opinion in this case as to whether or not fraying mesh can cause adverse patient consequences?
MS. KATZ GERSTEL: Objection.
A. I guess I don't know if -- if the mesh frays.

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And, you know, I will admit that, you know, mesh can -- there's an exposure rate; it's very low. And I haven't seen in my own experience frayed mesh. I would need to know more about what they're seeing and a bit more about those patients before, you know, passing judgment on -- on that.
BY MR. FAES:
Q. So you'd agree with me that there could be information that you haven't seen in this case that could change your opinions regarding the safety and efficacy of the TVT or TVT-O?
MS. KATZ GERSTEL: Objection.
A. I mean, it's possible. I mean, I haven't -- I haven't read every, you know, piece of paper that's -- that's out there. Sure, it's possible that there's something I haven't read that would, you know, change my idea about safety and efficacy. But after putting in 1200 slings, not seeing fraying; I'm not seeing significant exposures; I'm not seeing dyspareunia; I'm not seeing issues with, you know, clinical outcomes in the long term.
BY MR. FAES:

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Q. Would you agree that the TVT mesh is not designed to deform?
MS. KATZ GERSTEL: Objection.
A. I think that the TVT mesh is designed to be flexible with a certain amount of stiffness. I think that that's -- you know, besides the fact that you're placing it at the midurethra, I think that's the -- the level of stiffness also impacts some of the success of the TVT, not just the fact that it's at the midurethra, which I think is supported in the literature.
If you look at some of the head-to-head trials, Sparc versus TVT, they're relatively similar meshes, but the TVT is a little less stiff, and it also has a higher cure rate. And so it's not just that placing the mesh in the midurethra guarantees success. I think there's something to the biomechanical properties, as well.
But -- I didn't answer your question. The mesh is not -- they didn't design mesh with the idea for it to deform. They designed the mesh for it to support the midurethra.
BY MR. FAES:

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Q. So you would agree that if the TVT mesh were to become deformed or curled underneath the urethra, that would be an unintended consequence, correct?
MS. KATZ GERSTEL: Objection.
A. We try to place the slings underneath the midurethral flat without tension. I've not seen a sling that has curled or folded on itself or frayed. What I've seen are slings that are not positioned at the midurethra, and that's -- that's really the majority of what I've seen.
BY MR. FAES:
Q. But you would agree if that were to occur, it would be an unintended effect, correct?
MS. KATZ GERSTEL: Objection.
A. Well, I think it would be unintended for anyone to place a sling improperly, and I think it would be unintended for the sling to not sit, you know, flatly against the urethra.
MS. KATZ GERSTEL: Can I ask how we're doing on time?
MR. FAES: We've got, like, seven minutes or so.

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BY MR. FAES:
Q. I'm going to hand you two exhibits, Doctor, because I'm running out of time.
A. Okay.
Q. Exhibit 11 and 12.
MR. FAES: I'm getting yours.
(Deposition Exhibit No. 11 was marked for identification.)
MR. FAES: That's 11.
(Deposition Exhibit No. 12 was marked for identification.)
BY MR. FAES:
Q. And Exhibit No. 11 is an article published by you titled Management of Persistent Groin Pain After Transobturator Slings.
Do you see that?
A. (Examining document) Yeah.
Q. And the first sentence of the abstract is prolonged groin pain after transobturator tape is uncommon.
Do you see that?
A. Yes.
Q. And then if you look at Exhibit No. 12, this is another article by you in -- published in

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2010 titled: Pre-ramus passage of inside-out transobturator sling. Is that correct?
A. (Examining document) Yes.
Q. And the first sentence of that abstract is, groin pain after transobturator tape is not uncommon; is that correct?
A. Correct. Mm-hmm.
Q. So just looking at Exhibit No. 7, if you turn to the second page, second column, and you state in that article: Conceivably the proximity of the mesh to a branch of the anterior obturator nerve may cause compression and entrapment, parentheses, before entering the thigh, the obturator nerve divides into an interior and posterior branch. Then the anterior branch travels superficial to the internal obturator muscle but deep into the pectineus and adductor longus muscle, and then it travels superficial to the adductor brevis muscle; and finally the motor branches arise distal the obturator foramen and supply the adductor brevis, adductor longus and gracilis muscles. Interior branch entrapment may lead to exercise-related pain or may consist of

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groin pain.
Do you see that?
A. Yeah.
Q. Now, this published -- this article was published in 2007, correct?
A. Yes.
Q. And this is specifically treating a sling that a patient had been treated with using the obturator approach?
A. So this -- this article was basically a case series of three women who had persistent groin pain after -- specifically after an outside-in transobturator sling, the Monarc.
Q. And at this time in 2007, the TVT-O had actually been around for about three years and the Monarc sling a little longer than that, right?
A. Correct.
Q. And do you know that this article is actually cited quite frequently by other items in the literature for the proposition that the TVT-O can actually cause groin pain due to its proximity to the adductor muscles?
MS. KATZ GERSTEL: Objection.

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A. I'm kind of familiar with the article being cited a lot. I don't know -- you know, both TOTs and TVT-Os go through the medial compartment of the thigh so...
BY MR. FAES:
Q. Do you know whether or not -- well, strike that.
First of all, would you agree that the fact that this 2007 article is quite frequently cited for that proposition indicates that this was potentially new or novel information to the medical community as of 2007?
MS. KATZ GERSTEL: Objection.
A. I -- I don't think so. I mean, I think that I just, you know, wrote about my experience in dealing with these three patients, and in all likelihood other people were having -- were finding similar issues. It was just I was quicker to write about it than other folks.
BY MR. FAES:
Q. Would you agree that the evolution of one of your conclusions in the article from 2007, from prolonged groin pain with transobturator tape

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is uncommon to groin pain after a transobturator tape is not uncommon, reflects an evolution in the understanding of how common groin pain following a transobturator tape procedure was between 2007 and 2010?
MS. KATZ GERSTEL: Objection.
A. I mean, the point of -- the point of my language in the first paper where I say prolonged groin pain after transobturator tape is uncommon was to point out that it is uncommon, number one; and number two is because it's uncommon, here are three cases of people who had this uncommon event.
My language in the other article, in the abstract, which again is a distillation of the article, I start off the abstract with groin pain after transobturator tape is not uncommon. But I also didn't preface it by saying prolonged groin pain. I just said that, you know, out there people experience some groin pain after transobturator routes of surgery.
But then I think that later on in both articles I talk about how the groin pain is

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usually self-limited, and it's pretty uncommon to see groin pain, you know, after, let's say, three weeks.
BY MR. FAES:
Q. Have you seen documents in your review in issuing your opinions in this case indicating that Ethicon and Johnson & Johnson, as early as 2004, believed that persistent groin pain with the TVT-O was actually common and were already considering changes to the design of the device to address that issue less than three months after the device had been launched in the United States?
MS. KATZ GERSTEL: Objection.
A. I don't remember seeing those documents.
MR. FAES: Off the record for a second.
(Off-the-record colloquy.)
MR. FAES: Doctor, I have many more questions for you, but I'm informed I am out of time. So thank you for your time. I will let defense counsel conduct any questioning which she may have.
MS. KATZ GERSTEL: Thank you.
CROSS-EXAMINATION

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BY MS. KATZ GERSTEL:
Q. Dr. Roth, would it be fair to say that you have been implanting both the TVT retropubic and the TVT-O for some 13 years?
A. Yes.
Q. And I believe you testified that you've implanted a total of over a thousand TVTs and TVT-Os combined?
A. Easily, yes.
Q. Have the vast majority of your patients been happy with their results after having a TVT or a TVT-O implanted?
MR. FAES: Object to form.
A. The vast majority are very pleased with their outcomes, and I can't remember a specific patient who regretted her decision to have a sling.
BY MS. KATZ GERSTEL:
Q. For the vast majority of patients in whom you have implanted a TVT or a TVT-O, has their surgery improved their quality of life?
MR. FAES: Object to form.
A. Yes.
BY MS. KATZ GERSTEL:

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Q. Do most patients in whom you implant a TVT or TVT-O have complications?
MR. FAES: Objection.
A. I guess it depends on how you define complications, but for the most part, people do quite well after slings that I implanted.
BY MS. KATZ GERSTEL:
Q. For patients who do have complications after TVT or TVT-O, in your hands, is their complication usually treatable?
MR. FAES: Object to form.
A. Yes.
BY MS. KATZ GERSTEL:
Q. And are their complications usually treatable conservatively?
MR. FAES: Object to form.
A. Yes.
BY MS. KATZ GERSTEL:
Q. Do you regularly read the peer-reviewed medical literature --
(Off-the-record colloquy.)
BY MS. KATZ GERSTEL:
Q. Do you regularly read the peer-reviewed medical literature on midurethral slings

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including TVT and TVT-O?
MR. FAES: Object to form.
A. Yes.
BY MS. KATZ GERSTEL:
Q. Do you confer with your medical colleagues about midurethral slings including TVT and TVT-O?
MR. FAES: Object to form.
A. Yes.
BY MS. KATZ GERSTEL:
Q. Do you attend medical society conferences at which TVT and TVT-O are discussed?
A. Yes.
Q. Are your opinions on TVT and TVT-O based on your own outcomes with the devices, as well as the peer-reviewed medical literature?
MR. FAES: Object to form.
A. Yes.
BY MS. KATZ GERSTEL:
Q. Do you recall that Mr. Faes asked you some questions about laser-cut mesh versus mechanically-cut mesh?
A. I remember those questions.
Q. Is it correct that TVT comes both as a

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mechanically-cut -- strike that.
Do you agree that TVT can have mechanically-cut mesh or laser-cut mesh?
A. Yes. They -- I think the Exact only comes as laser-cut, but the regular retropubic can come as both laser- or mechanically-cut. And the Abbrevo, I think, is laser-cut and the TVT-O can come as laser-cut or mechanically-cut. But I use just the mechanically-cut material.
Q. Dr. Roth, whether it's mechanically-cut or laser-cut -- strike that.
Doctor, if the TVT has laser-cut mesh or mechanically-cut mesh, regardless of whether it has -- strike that. Start over.
Doctor, regardless of whether a TVT has laser-cut mesh or mechanically-cut mesh, it's still a TVT; is that correct?
A. Yes.
Q. And regardless of whether a TVT-O has a laser-cut mesh or a mechanically-cut mesh, it's still a TVT-O; is that correct?
A. Yes.
Q. Is it true that -- strike that.
Are you aware of any peer-reviewed

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medical literature that has ever shown any different outcomes for patients whether they've had a mechanically-cut mesh or a laser-cut mesh?
MR. FAES: Object to form.
A. I'm not aware of any publications in that regard, no.
BY MS. KATZ GERSTEL:
Q. Are you aware of any evidence whatsoever from any source that has ever shown different outcomes for patients according to whether they've had a mechanically-cut mesh or a laser-cut mesh?
MR. FAES: Object to form.
A. No, I'm not aware of that.
BY MS. KATZ GERSTEL:
Q. And yourself having implanted more than a thousand TVTs and TVT-Os, have you ever seen any clinical differences in outcomes between laser-cut mesh and mechanically-cut mesh?
MR. FAES: Object to form.
A. No.
BY MS. KATZ GERSTEL:
Q. Doctor, do you recall that Mr. Faes asked you

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some questions about blue mesh versus clear mesh?
A. Yes.
Q. Are you aware of any evidence whatsoever from any source indicating that patients have different outcomes depending on whether they've had a blue mesh or a clear mesh?
MR. FAES: Object to form.
A. No.
BY MS. KATZ GERSTEL:
Q. And have you ever seen in your own practice a difference in outcomes for patients depending on whether they've had a blue mesh or a clear mesh?
MR. FAES: Object to form.
A. No.
BY MS. KATZ GERSTEL:
Q. Do you recall Mr. Faes asking you about the pore size of the mesh used in TVT and TVT-O?
A. Yes.
Q. Are you aware of whether the mesh in TVT and TVT-O are macroporous type 1 meshes?
MR. FAES: Object to form.
A. They're macroporous type 1 meshes.

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BY MS. KATZ GERSTEL:
Q. Why is it -- strike that.
Is it your understanding that type 1 macroporous meshes are the most -- well, strike that.
Is it your understanding that type 1 macroporous polypropylene meshes are the best tolerated meshes to use in the human body?
MR. FAES: Object to form.
A. In terms of their use in the vagina and also for abdominal repairs that I do, sacrocolpopexies, those are the safest meshes.
(Off-the-record colloquy.)
Q. And can you explain why it's important that -- strike that.
Doctor, do you recall Mr. Faes asking you some questions about what you are an expert in?
A. Yeah.
Q. Having implanted over a thousand TVTs and TVT-Os and then followed your patients for years afterwards, is it fair to say that you're an expert in how a woman's body reacts to the implantation of TVT or TVT-O?

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MR. FAES: Object to form.
A. I think that's fair.
BY MS. KATZ GERSTEL:
Q. As a surgeon who has implanted over a thousand TVTs and TVT-Os combined, are you an expert in how the design of the TVT and TVT-O avoids unintended trauma?
MR. FAES: Object to form.
A. Yes.
BY MS. KATZ GERSTEL:
Q. As a surgeon who has implanted over a thousand TVTs and TVT-Os combined, are you an expert in how the design of the TVT and TVT-O minimizes the potential for complications?
MR. FAES: Object to form.
A. Yes.
BY MS. KATZ GERSTEL:
Q. As a surgeon who was trained in non-mesh anti-incontinence surgeries and has implanted over a thousand TVT-Os and TVTs combined and who regularly reads the peer-reviewed medical literature on midurethral slings and confers with colleagues on midurethral slings, are you an expert in what risks pelvic surgeons are

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aware of before they do a midurethral sling surgery?
MR. FAES: Object to form.
A. Yes.
BY MS. KATZ GERSTEL:
Q. And are you thereafter an expert in what warnings pelvic surgeons would need to be given prior to performing a TVT or TVT-O?
MR. FAES: Object to form.
A. Yes.
BY MS. KATZ GERSTEL:
Q. Is it your opinion that the design of the TVT makes it a safe and effective device?
MR. FAES: Object to form.
A. Yes.
BY MS. KATZ GERSTEL:
Q. Is it your opinion that the design of the TVT-O makes that a safe and effective device?
MR. FAES: Object to form.
A. Yes.
BY MS. KATZ GERSTEL:
Q. And can you explain how the design of the TVT-O, promotes its safety and efficacy?
A. I mean, the idea behind the obturator sling

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was to change the complication profile of a retropubic approach, specifically perforating the bladder, bowel, and great vessels of the pelvis.

The TOT, which came out prior to the TVT-O was a novel approval whereby the trocars were passed through the -- the groin, ischiorectal or superior aspect -- aspect of the ischiorectal fossa, paravaginal space and then into the vagina so that we're not getting anywhere near the bladder, the bowel, or the pelvis.

The innovation of the TVT-O, which in my mind I favor over the TOT, is that you're starting at the mid-vagina, which is important for the efficacy of these procedures. But the sling is placed at midurethra or very close to what's considered to be the midurethra.

And then passage of the device from inside to out again in my mind is safer from inside to out than outside to in because of the anatomy and how the obturator neurovascular bundle presents itself to the sling.

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From outside to in, the neurovascular bundle runs along the outside of the obturator foramen. So if you're going from outside to in, in my mind and in some papers, you have a greater risk of injuring that neurovascular bundle because it's in front of the bone.

If you're coming from inside to out, that neurovascular bundle is naturally protected because it's running around the outer rim of the bone.

So I think you have, you know, greater protection and greater safety with the TVT-O versus the TOT, although I think that most of your meta-analyses, systematic reviews probably find that there's really not a significant difference in terms of safety of inside-out versus outside-in.

Q. And can you explain how the design of the TVT promotes the safety and efficacy of that device?

A. So, you know, the original pubovaginal slings that we were doing there was a means of you had to affix the sling to either the rectus fascia or the retropubic space with bone anchors. If you weren't using a full length piece of material, then you would do essentially what was known as a sling on a string, and you would attach suture tails to the end of the sling, but you would still have to go above, make an incision to fix the material there.

The novel thing about the TVT is that although you are still going retropubically, you no longer have to affix the material to the rectus fascia or to the -- the pubic bones with bone anchors. You have essentially an anchorless system, which requires less dissection, less invasive. And, you know, in my mind people have significant -- there were case reports of people developing osteomyelitis with the bone anchors and other sorts of infections, seromas, with the pubovaginal sites.

Q. Doctor, does the IFU for the TVT and TVT-O, do those include every single possible complication attendant to the implantation of those devices?

MR. FAES: Object to form.

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A. You know, I don't think that the IFUs contain every conceivable possible complication from -- from those devices, but I think that they contain the -- what's relevant to not only the implanting surgeon but also to the patients.

BY MS. KATZ GERSTEL:

Q. Do the IFUs need to contain every single possible complication for the TVT and TVT-O?

MR. FAES: Object to form.

A. I think that a lot of what's contained in the IFUs -- the majority of what's contained in the IFUs are well-known complications to pelvic surgeons, urologists, urogynecologists, people doing incontinence surgery. So I don't think that an exhaustive list of complications is necessary, and I also don't think that it would impact patient care or decision-making for -- for that surgeon to do that procedure.

BY MS. KATZ GERSTEL:

Q. Doctor, if you have dinner with a sales rep from a medical device or pharmaceutical company, do you receive cash?

A. No. I just -- I just get dinner.

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Q. Doctor, do you recall that Mr. Faes asked you some questions about the work that you've done with various medical devices and pharmaceutical companies?
A. Yes.
Q. Has the work that you've done with medical devices and pharmaceutical companies mostly involved teaching or instructing other surgeons and doctors?
MR. FAES: Object to form.
A. Yeah. I mean, the majority of what I was contracted to do by J & J and what I still continue to do for Medtronic is teaching other -- other physicians how to do procedures.
There was maybe one event where -- well, there may be a few events where J & J brought a lot of implanters and had us congregate for us to discuss pearls, tips, tricks to get our opinions and to sort of see how things were going for their -- for feedback.
But the majority of what I was contracted to do was to -- was to teach both at my facility, at a doctor's facility and also at

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cadaver labs.
BY MS. KATZ GERSTEL:
Q. Doctor, would you ever do work, including speaking and teaching, for a medical device or pharmaceutical company if you believed that the safety and efficacy of the products you were speaking or teaching about were not supported by medical evidence?
MR. FAES: Object to form.
A. Yeah, no, I try to be pretty ethical. I wouldn't -- if I felt like the TVT products were unsafe or didn't have good outcomes, I -- number one, I wouldn't attend them; and, number two, I certainly wouldn't teach other people how to do it.
And the same thing for my relationships with the drug companies; I wouldn't get up in front of a group of people and tell them about a drug if it was unsafe or not effective.
BY MS. KATZ GERSTEL:
Q. Doctor, you were asked about an Exhibit 8, which is a contract that you had with Ethicon, dated April 30th of 2009. On the page ending in 0275 under number 12, you were asked about

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this clause, which states, you shall not make any representation relating to companies' products or to companies' clinical outcomes unless such representations have been reviewed and approved in advance by a company.
A. Mm-hmm.
Q. Do you recall being asked about that?
A. Yeah.
Q. Doctor, did you ever make any representations to doctors you were teaching, according to this contract with Ethicon, that you did not believe were accurate or supported by the medical evidence?
MR. FAES: Object to form.
A. I did not.
BY MS. KATZ GERSTEL:
Q. Doctor, you were also asked about Exhibit 9, which is a chain of e-mails between you and personnel at your hospital.
Do you recall those questions?
A. Yes.
Q. And on the first page of Exhibit 9, the page ending in 6013, this is an e-mail that you sent to Steve Gauthier, James Hagen, copying

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Laird Covey and Lisa Ledoux; is that correct?
A. Yes.
Q. And when you drafted this e-mail, on March 14, 2009, were you working as an expert for Ethicon at this time?
A. I was working as a proctor and preceptor at that point.
Q. And you were not working as an expert yet; is that correct?
A. An expert in regards to mesh --
Q. Litigation expert.
A. No.
Q. Doctor, I want to read a couple of sentences from this e-mail. Going down to about the middle of the page did you write in this e-mail: These products, meaning the Johnson & Johnson products that you were going to be preceptoring on, these products are FDA approved, rigorously studied and are what I would recommend to my family members.
A. I wrote that, yes.
Q. And then right below that did you write the following: I'm approached weekly by other device companies to use their products and

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become preceptors from them. I favor J & J since I've had about a decade of experience with their products, and again, they are the most rigorously studied products.
A. Yes, I wrote that.
Q. And then turning on to the third page which ends in 6015.
Is this another e-mail that you wrote? It actually starts on the bottom of 6014.
A. Yes. This is -- that's part of the e-mail on 6014, correct.
Q. And so looking back at 6015, do you see where it starts: Patients are not being brought to the OR?
A. Okay. Yeah, I see -- I see where you are now, yeah.
Q. Patients are not being brought to the OR to use J & J products. They are being brought to the OR to have surgery to correct specific problems. I choose to use J & J products since they have the most data to support them out of all the possible medical device companies that make products for incontinence and prolapse. These procedures are done

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according to strict guidelines and no deviation -- I don't know what the next word is -- and then it says standard of care.
Did I read that correctly?
MR. FAES: Object to form.
A. Yes. As much as I typed it incorrectly, you read it correctly.
BY MS. KATZ GERSTEL:
Q. Doctor, do you practice evidence-based medicine?
MR. FAES: Object to form.
A. Yes.
BY MS. KATZ GERSTEL:
Q. What is evidence-based medicine?
A. It's medicine and surgery based upon what's been shown to be effective and safe in the medical literature.
Q. How is it helpful to your patients to practice evidence-based medicine?
A. I think by offering them what is evidence-based medicine, they're getting the best -- that might be too strong but the -- they're getting the procedure, the treatment, the medicine that has been vetted and studied

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the most, as opposed to me offering them some sort of treatment that hasn't been rigorously studied, vetted, you know, something that is based on anecdotal, you know, single case report. Evidence-based medicine is based on, you know, specific trials, powered investigations, adequate, you know, control groups and rigorous assessment of outcomes.
Q. Doctor, could you please turn to page 6 of your report?
A. Okay.
Q. Do you see the sentence down at the bottom that Mr. Faes asked you about, MUS, including TVT and TVT-O, are taught in residency and fellowship programs throughout the United States and are the gold standard procedure for SUI?
A. Yes.
Q. Do you recall Mr. Faes asking you some questions about this statement?
A. Yes.
Q. Are TVT and TVT-O among the midurethral slings that Serati was talking about?
A. Yes.

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Q. Could you turn to page 9, please. And can -- do you see the sentence: Over 80 percent of women with SUI are cured or have significant improvement in their symptoms with either retropubic or transobturator route MUS for up to five years after surgery?
A. Yes.
Q. And that's a statement that is from the Ford 2015 Cochrane paper; is that correct?
A. Correct.
Q. And are TVT and TVT-O included in the midurethral slings that are being referenced there?
A. Yes.
Q. Doctor, do you remember that Mr. Faes asked you some questions about patient satisfaction?
A. Yes.
Q. Could you please turn to page 15 of your report?
A. Okay.
Q. Do you include a discussion here under Retropubic Versus Transobturator Midurethral Slings about the Laurikainen 2014 paper?
A. You're on page 15?

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Q. Yes.
A. Yes.
Q. And did the Laurikainen paper discuss patient satisfaction?
A. Excuse me. Yes, it did. It addressed subjective success, and it's a patient-reported outcome.
Q. This sentence in the middle of the paragraph, it starts 92.6 percent.
Do you see where I'm reading?
A. Yes.
Q. I'll just read that sentence. 92.6 percent of women in the TVT group and 88.6 percent of the women in the TVT-O group reported that they would recommend the procedure to a friend.
Doctor, is that an indication of patient satisfaction?
MR. FAES: Object to form.
A. Yes.
BY MS. KATZ GERSTEL:
Q. Doctor, is a 19 percent exposure or tape projection rate something that you have seen in your own practice?
MR. FAES: Object to form.

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A. No.
BY MS. KATZ GERSTEL:
Q. Is a 19 percent exposure or tape projection rate a rate that has been reported in the meta-analyses and systematic reviews of randomized controlled trials on midurethral slings, including TVTs and TVT-Os?
MR. FAES: Object to form.
A. I don't think that any of the meta-analyses or systematic analyses reported rates anywhere close to 19 percent.
BY MS. KATZ GERSTEL:
Q. Could you please look at page 19 of your report?
Under Mesh Exposure/Extrusion in your report, did you discuss the Funk study from 2013?
A. (Examining document) I did.
Q. And can you tell us what that study found in terms of risk of reoperation due to exposure or erosion?
A. Sure. So that was a population-based study. I can't remember the database that they accessed, but it's a pretty extensive number

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of patients, 188,454 women who underwent sling revision, removal of mesh. The -- ultimately the nine-year risk of -- or the nine-year cumulative risk of reoperation was 3.7 percent with a risk of mesh erosion, slash, exposure of 2.5 percent.
But with that being said, there were some limitations to that in terms of not knowing when they presented, not knowing what sling was placed, et cetera, et cetera. But that's a very low rate of erosion for a very large number of patients, which is consistent with my personal experience.
Q. Does the Funk study show that there was a nine-year cumulative risk of 3.7 percent of the sling revision or removal due to mesh erosion and retention?
A. That's correct.
Q. Doctor, in formulating your opinions, do you base your opinions on the peer-reviewed medical literature?
MR. FAES: Object to form.
A. Yes.
BY MS. KATZ GERSTEL:

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Q. In formulating your opinions, do you base your opinions on highest level of evidence available?
MR. FAES: Object to form.
A. I try to make my opinions based on the meta-analyses and systematic reviews, which are the highest levels of evidence available.
BY MS. KATZ GERSTEL:
Q. Does the highest level of evidence in the medical literature consist of systematic reviews and meta-analyses?
A. Yes.
Q. And is that why you cited the Nager commentary on page 7 of your report which aggregates the results of four systematic reviews and meta-analyses?
MR. FAES: Object to form.
A. Yeah. That's why I -- I put that chart in, because it's a very nice summation of midurethral slings versus other incontinence procedures and the results based on those four meta-analyses.
MS. KATZ GERSTEL: That's all I have.
THE WITNESS: Sure.

MR. FAES: Until tomorrow.
MS. KATZ GERSTEL: Yes.
(The deposition concluded at 4:45 p.m.)

DEPONENT SIGNATURE PAGE

CAPTION: IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION
DEPONENT: TED M. ROTH, M.D.

I, TED M. ROTH, M.D., acknowledge that I have read Pages 1 through 242 inclusive of the transcript of my deposition taken on March 16, 2017. I further acknowledge that:
(check appropriate language)

_____ the same is a true, correct, and complete transcription of the answers given by me to the questions recorded therein.

OR

_____ except for the changes noted on the attached errata sheet, the same is a true, correct, and complete transcription of the answers given by me to the questions recorded therein.

_____
TED M. ROTH, M.D.

Subscribed and sworn to before me this_____ day of_____, 2017

_____
Notary Public

CERTIFICATE

I, Beth Gaige, a Registered Professional Reporter and Notary Public in and for the State of Maine, hereby certify that the within-named deponent was sworn to testify the truth, the whole truth, and nothing but the truth in the aforementioned cause of action.

I further certify that this deposition was stenographically reported by me and later reduced to print through computer-aided transcription, and the foregoing is a full and true record of the testimony given by the deponent.

I further certify that I am a disinterested person in the event or outcome of the above-named cause of action.

IN WITNESS WHEREOF, I subscribe my hand and affix my seal this 28th day of March 2017.

_____
Beth Gaige, RPR
Notary Public
My commission expires:

THE ORIGINAL DEPOSITION OF TED M. ROTH, M.D.
SHOULD INCLUDE THE FOLLOWING CORRECTIONS:

_____

TED M. ROTH, M.D.